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SB 138
SPONSOR STATEMENT

"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."

The Federal Food and Drug Administration has the obligation and authority to research prescriptive medicines. As a result, officials require the use of potentially dangerous drugs to be prescribed and supervised by a qualified medical professional. Over approximately the past decade, some medical professionals who are not licensed medical doctors have been empowered to write prescriptions for some classes of prescription drugs.

Across the country, states have allowed in statute for collaborative agreements that permit medical professionals, to whom we have given "prescriptive authority", the freedom to have formal agreements with pharmacists who may then prescribe some classes of medicines under the specific authority and supervision of the authorized medical professional. These agreements have facilitated the delivery of medicines to Alaskan citizens, particularly in rural Alaska.

Last year the Alaska Pharmacy Board issued new regulations that allow for "collaborative agreements" that allow virtually no relationship between a specific doctor and a specific patient. Governor Knowles signed these regulations over the strong objection of the State Medical Board and the Alaska State Medical Association. Currently, some doctors are entering in "collaborative agreements" wherein the pharmacist issues potentially dangerous drugs to patients and customers that have no connection to that doctor or necessarily any doctor. The only relationship is that the pharmacist faxes or emails, every three months, a list of the customers who receive the drugs. **This destroys the value of the F.D.A.'s work in classifying some drugs as dangerous enough to require a specific doctor's prescription.** Because of the potentially unsafe dispensing of prescription drugs and the lack of appropriate medical supervision, SB 138 aims to annul the regulations that allow collaborative practice agreements and to prevent further agreements from being forged.

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

April 11, 2003

Honorable Fred Dyson
State of Alaska
Senate
Chair, Senate Health, Education and Social Services
State Capitol, Room 121
Juneau, AK 99801

Re: SB 138 – Collaborative Practice Authority by a Pharmacist; Annul 12 AAC 52.240

Dear Senator Dyson:

The Alaska State Medical Association (ASMA) represents Alaska's patients and the physicians who care for them. Thank you for the opportunity to testify on SB 138.

ASMA supports the passage of SB 138. SB 138 annuls a regulation, 12 AAC 52.240, which allows a pharmacist to either initiate or modify a drug therapy as long as a collaborative agreement and written protocol is entered into with a practitioner who has the authority to prescribe drugs. Those statutorily authorized practitioners are physicians, dentists, physician assistants, and nurse practitioners. 12 AAC 52.240 was adopted by the Board of Pharmacy and covers any drug able to be prescribed.

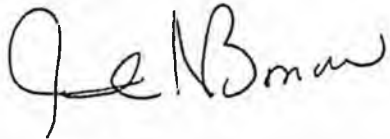
ASMA provided written testimony in opposition to the adoption of this regulation (see attached written comments dated December 13, 2000). ASMA continues to oppose these regulations for among the following reasons:

1. The Board of Pharmacy does not have sufficient statutory authority to adopt such a regulation and to reach beyond its regulatory scope to other regulated professions (e.g. physicians);
2. A physician would jeopardize her/his license by entering into such an agreement with a pharmacist. A physician cannot delegate duties to a person not appropriately licensed to perform those duties;
3. Under such arrangements, it is possible for a patient to never see a physician, but yet receive a prescription drug; and
4. 12 AAC 52.240 does not enhance the already good standard of care in Alaska.

ASMA is very concerned about the potential for harm to patients. The level of concern is such that ASMA's Board of Trustees has been directed by its policy making body, the House of Delegates, to explore legal as well as other available remedies, such as SB 138. Circumstances may exist involving an ongoing patient/physician relationship when such arrangements might work. However, such circumstances must be provided for in laws enacted by the Legislature and not by inappropriate regulatory fiat.

Attached is a document that outlines legal considerations, policy considerations, and conclusions, which elaborate on this issue.

Sincerely,

A handwritten signature in cursive script that reads "Jeanne Bonar". The signature is written in black ink and is positioned above the typed name.

By: Jeanne Bonar, MD
President

For: Alaska State Medical Association

I. Legal Consideration

- AS 08.80.030 does not give the Pharmacy Board the authority to adopt these specific regulations. It is a catchall provision that empowers it to adopt a regulation for which it has statutory authority to adopt.
- AS 08.80.480 (27) defines the practice of pharmacy as the ability to dispense a "prescription drug order".
 - "Prescription drug order" is defined under AS 08.80.480 (31) as the lawful order of a "practitioner" for a drug or device for a specific patient.
 - "Practitioner" is defined in AS 08.80.480(28) as an individual currently licensed to prescribe and administer drugs in the course of professional practice. (physician, ANP, dentist, PA)
 - Pharmacists can only dispense with a collaborative agreement drawn tightly enough so that it is really a "drug order" with very specific conditions for filling and re-filling. It is legally questionable whether a collaborative agreement could be drawn with enough specificity to become a prescriptive drug order.
- In AS 08.64.107 the Legislature has set up the framework for physicians to engage in collaborative activities with other health care providers. The categories of other health care providers covered are PA's and intensive care paramedics. The State Medical Board has adopted extensive regulations concerning the physician's relationship with those categories of health care providers. The Legislature has set up categories for collaborative arrangements, but they did not include pharmacists.
- 12 AAC 40.967 (8), a regulation pertaining to unprofessional conduct, makes it an act of "unprofessional conduct" for a physician to delegate a professional practice responsibility that requires a license to another without that authority. So, a physician cannot enter into a collaborative arrangement with a pharmacist unless it meets the criteria for a "drug order" without facing the possible administrative action that could result in fines, license suspension, or license revocation.
- It appears that the only exceptions the SMB could make are those provided for in the statutes. Specifically, AS 08.164.107, which sets up collaborative arrangements only for PAs and intensive care paramedics.

II. Policy and Other Considerations

- The SMB has no part in determining a collaborative arrangement reaches the specificity and level of a "drug order".
- 12 AAC 40.990 (25) describes "health care professional". There is a long laundry list but "pharmacist" is not found on that list. This is a regulation adopted by the SMB. So, a physician is not in a good position to enter into a collaborative agreement with a professional that the SMB has not termed a health care provider.
- Important questions are not answered nor provided for in the regulations.
 - Is there a physician/patient relationship created when a pharmacist prescribes under a collaboration agreement? (When does it start? When does it end?)
 - Is there vicarious liability that attaches to the physician? (Does the physician's professional liability insurance provide coverage?)
 - Is it good medicine for such a patient to perhaps never be seen by a physician?
 - How do such relationships affect what constitutes the standard of care?
 - How is informed consent provided for?

III. Conclusions

- Pharmacy Board has insufficient statutory authority to adopt such a regulation and to reach beyond its regulatory scope to other regulated professions (e.g. physicians).
- A physician jeopardizes his/her license by entering into such an agreement with a pharmacist.
- A potentially harmful situation is created when it is possible for a patient never to see a physician, but receive prescription drugs.
- Circumstances exist that might provide for such arrangements to work well, when an ongoing patient/physician relationship exists.

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

December 13, 2000

Honorable Deborah B. Sedwick
State of Alaska
Department of Community and
Economic Development
PO Box 110806
Juneau, Alaska 99811-0806

Transmitted by Fax: 907-465-2974

Attention: Kurt West

RE: Written Comments on Proposed Board of Pharmacy Regulations Noticed October 16, 2000

Dear Commissioner Sedwick:

The Alaska State Medical Association (ASMA) represents Alaska's patients and the physicians who care for them. The purpose of this letter is to comment on the regulations proposed by the Board of Pharmacy noticed on 10/16/00. ASMA will limit its commentary to proposed section 12AAC 52.240 and 12AAC 52.250.

In general, it is ASMA's opinion that insufficient statutory authority exists to adopt 12AAC 52.240 and 12AAC 52.250. Additionally, these proposed sections would also change the regulation of the practice of medicine by allowing a physician to delegate a duty. The Board of Pharmacy does not have the jurisdiction to do so.

The statutory authority for both of these sections as listed in the proposed regulation is AS 08.80.030 and AS 08.80.480. AS 08.80.030 gives the general authority to the Board of Pharmacy. Presumably, the cite relied upon is the general authority to adopt regulations at AS 08.80.030(b)(4). This section does not address collaborative arrangements with any practitioner authorized under AS 08 to prescribe drugs.

AS 08.80.480 is the "Definition" section of the Pharmacy Act. There is no provision that refers to collaborative arrangements with any practitioner authorized under AS 08 to prescribe drugs. Because the statutory authority listed is for the entire section, one can only surmise as to which subsection is being relied on. Presumably, that subsection is AS 08.80.480 (27), which defines the term "practice of pharmacy." Again, nothing in this subsection pertains to collaborative arrangements with any practitioner authorized under AS 08 to prescribe drugs. One can only guess that the collaborative arrangements would fall under the general rubric of a "prescription drug order." ASMA asserts that this is an inappropriate and illegal expansion of the law's intent by regulatory fiat.

Given this absence of direct statutory authority, ASMA asserts that such a change as proposed can only be enacted by the passing of a new law by the Legislature which specifically authorizes such collaborative arrangements. Furthermore, any such law would need to change the practice acts for all practitioners authorized to prescribe drugs under AS 08 to allow such a delegation as is proposed under 12AAC 52.240. Additionally, it would also have to be either drug specific; or provide for a determination as to which drugs would be allowed to be prescribed and dispensed in this manner be made by all of the regulatory boards for the practitioners authorized to dispense. The Pharmacy Board needs the official consultation from other boards such as the State Medical Board. The criteria for the protocols and the collaborative arrangement would also need to be developed in more detail than that found in 12AAC 52.240.

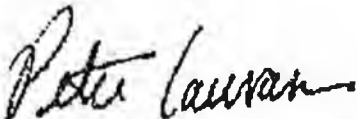
Proposed 12AAC 52.240 (b) (5) indicates that any protocol must include a list of the types of patients eligible to receive drugs under a collaborative arrangement. This criterion is broad enough to allow persons to receive drugs who are not patients of the collaborating practitioner. Two important issues are raised by this situation. First, it's possible for a person to receive a prescription without being seen by a physician. This is not good patient care. Second, such a situation would provide for problematic liability issues. Issues of vicarious liability are raised for the collaborating physician. Such issues can lead to professional liability insurance coverage issues for physicians and most likely would lead to increased professional liability premiums. The negative impact of both circumstances is obvious.

Again, ASMA recommends that the proposed regulations subject of this letter not be adopted because:

1. insufficient statutory authority exists;
2. the regulatory "reach" to other licensed professions (e.g., physicians) is beyond the authority of the Pharmacy Board; and
3. such major changes in the scope of practice for pharmacists and the delegation of practice responsibility (prescribing drugs) is more appropriately in the domain of the Legislature.

We suggest you seek legislation in order to make the major changes that you propose. Such a major change in scope of practice should not be accomplished by a regulatory fiat based on questionable, if not, non-existent statutory authority.

Sincerely,



By: Peter Lawrason, MD, President

For: Alaska State Medical Association

JJJ/



STATE OF ALASKA
DEPARTMENT OF COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF OCCUPATIONAL LICENSING
BOARD OF PHARMACY
P.O. BOX 110806, JUNEAU, ALASKA 99811-0806
(907) 465-2589
E-mail: license@dced.state.ak.us

PHARMACIST COLLABORATIVE PRACTICE APPLICATION

Instructions: Complete this application form and submit, along with the written protocol, to the above address for approval by the board. For hospitals with protocols approved by the hospital pharmacy and therapeutics committee, an "umbrella protocol" that meets all of the requirements of 12 AAC 52.240(b) may be accepted by the board.

Title of Protocol: _____

Principal Pharmacist:

Name License # _____

For protocols involving multiple pharmacists, list participating pharmacists and license numbers, or identify by description those participating (ie; all pharmacists employed by XYZ Pharmacy): _____

Practice Site:

Pharmacy Name License # _____

Street Address

City/State/Zip Code

Telephone Number: _____

Principal Authorizing Prescriber:

Type of License: _____

Name License # _____

For protocols involving multiple prescribing practitioners, list participating practitioners and license numbers, or identify by description those participating (ie; all staff physicians at XYZ Hospital): _____

Practice Site: _____

Street Address

City/State/Zip Code

Telephone Number: _____

CONTINUED ON REVERSE SIDE

Required in accordance with 12 AAC 52.240(b)

	YES	NO
(1) Does the protocol contain an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol?.....	<input type="checkbox"/>	<input type="checkbox"/>
(2) Does the protocol contain a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement?.....	<input type="checkbox"/>	<input type="checkbox"/>
(3) Is a time period for the protocol specified? (May not exceed two years).....	<input type="checkbox"/>	<input type="checkbox"/>
(4) Does the protocol include the types of collaborative authority decisions that pharmacists are authorized to make, including		
(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case?	<input type="checkbox"/>	<input type="checkbox"/>
(B) Procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved?	<input type="checkbox"/>	<input type="checkbox"/>
(5) Does the protocol include the activities that pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning the specific decisions made?.....	<input type="checkbox"/>	<input type="checkbox"/>
(6) Does the protocol contain a list of the specific types of patients eligible to receive services under the written protocol?	<input type="checkbox"/>	<input type="checkbox"/>
(7) Does the protocol include a plan for the authorizing practitioners to review the decisions made by the pharmacist at least once every three months?.....	<input type="checkbox"/>	<input type="checkbox"/>
(8) Does the protocol include a plan for providing the authorizing practitioners with each patient record created under the written protocol?	<input type="checkbox"/>	<input type="checkbox"/>
(9) Are the authorizing practitioners in active practice, and is the prescriptive authority within the scope of the practitioners' practice?.....	<input type="checkbox"/>	<input type="checkbox"/>
(10) Does the protocol specify and require completion of additional training, if required for the procedures authorized under the protocol?.....	<input type="checkbox"/>	<input type="checkbox"/>

Also please note:

- Documentation related to the written protocol must be maintained for at least two years.
- The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.
- Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

Signature of Principal Pharmacist

Signature of Principal Prescriber

Date

Date

CONTINUED ON NEXT PAGE

COLLABORATIVE PRACTICE REGULATIONS

12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY. (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.

(b) A written protocol must include

(1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;

(2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;

(3) the time period during which the written protocol will be in effect, not to exceed two years;

(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including

(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case;

(B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;

(5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;

(6) a list of the specific types of patients eligible to receive services under the written protocol;

(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months; and

(8) a plan for providing the authorizing practitioners with each patient record created under the written protocol.

(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.

(d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

12 AAC 52.995. DEFINITIONS

(c) In AS 08.80.030(b)(7), "monitoring of drug therapy" means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Monitoring of drug therapy" includes

(1) collecting and reviewing records of patient drug use histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under 12 AAC 52.240.

THE
FOLLOWING
DOCUMENT(S)
ARE
POOR
ORIGINAL
COPIES

STATE OF ALASKA
DEPARTMENT OF COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF OCCUPATIONAL LICENSING

STATE MEDICAL BOARD

MINUTES OF MEETING

 OCTOBER 26-27, 2000

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a scheduled meeting of the Alaska State Medical Board was held on Thursday and Friday, October 26 and 27, 2000, in room 336 of the Frontier Building, Anchorage, Alaska.

Thursday, October 26, 2000

[Page 1, Side A]

The meeting was called to order by chair Dr. Sarah A. Isto at 9:20 am.

Present for roll call were:

Dr. Sarah Isto

Dr. Keith Brownsberger

Dr. Donald Olson

Sheila Means

Dr. Irvin A. Rothrock

Board staff members Joanie Stude, Leslie Abel, and Colin Matthews were also present. Visitors PA-C Jim Wojcichowski and PA-C Ed Hall were also in attendance.

AGENDA REVIEW

Dr. Isto noted that additional documents were distributed to board members to be added to the agenda. The board has been asked by the Division to add to the agenda a review of the renewal forms to be used this year and the new fee schedule. Catherine Reardon will join the meeting for this discussion.

NEW AGENDA ITEM

Review of Renewal Forms and New Fees

053

Dr. Brownsberger initially moved to approve the renewal forms and fees as presented.

[Dr. Cotten joined the meeting at 9:37 am.]

Director Catherine Reardon and Program Coordinator Barbara Gabler joined the meeting via telephone and discussed with the board the question of confidentiality of renewal forms. 216

The board discussed the language in three parts of the renewal forms on page 2 and proposed changes. Board members were particularly concerned with the wording of the "Confidentiality" paragraph.

MOTION

Upon a motion by BROWNSBERGER, seconded by MEANS, amended by MEANS, and carried without objection, it was

RESOLVED to adopt the renewal forms with the following changes on page 2:
under "Confidentiality," last sentence should read: "A request for confidentiality may or may not be granted." In question 2, insert "Alaska" before "State Medical Board." In question 7, remove the word "active" from in front of "investigation." 852

MOTION Upon a motion by LIVSEY, seconded by MEANS and carried without objection, it was RESOLVED that in accordance with AS 44.63.310(c)(2), the State Medical Board go into Executive Session for the purpose of discussing the matter of Glen W. Straatsma, MD.

250

Off the record at 9:20 am; on the record at 9:45 am.

Mr. Tiemessen noted that Dr Straatsma self-reported to the medical board; he suggested that a portion of the fine be suspended and tied directly to the fact that Dr. Straatsma came forward of his own volition. The board agreed with Mr. Tiemessen's view.

377

MOTION Upon a motion by BROWNSBERGER, seconded by LIVSEY, amended by COTTEN and BROWNSBERGER, and carried without objection, it was RESOLVED to restore Dr. Straatsma's license to active status with a memorandum of agreement with restrictions as specified by Ms. Fried [Straatsma's counselor], a requirement to abstain from alcohol, requirements for continuing treatment, quarterly reports to the board, to be of five years' duration, and to include a \$10,000 civil fine with \$5,000 suspended. The restoration of the license to be contingent upon the full execution of the memorandum of agreement.

425

Mr. Matthews advised that he would draft the MOA and circulate it to the board members to insure that all elements have been included.

Off the record at 9:55 am; on the record at 10:01 am.

A ↓
AGENDA ITEM

October 24-27 2000
Regulations Project: Collaboration Relationship Between Physicians and Pharmacists

Mark Bohrer, a Board of Pharmacy member, met with the board to discuss a proposed regulation from that board. Dr. Peter Nakamura joined the meeting via telephone and Dr. Colleen Murphy was present in person. Mr. Bohrer explained the Board of Pharmacy's intentions in introducing this regulation. He detailed the types of work that could be done by the pharmacist; he noted that the proposed regulations do fall within the scope of practice for pharmacists.

Dr. Brownsborger expressed his concerns about the proposed regulation including the responsibility of the physician to supervise the pharmacist. He indicated that he felt this was the practice of medicine. He felt this would put another individual between the physician and the patient that would hinder the provision of medical care from the physician.

610

[Tape 5, Side B]

Drs. Cotten and Isto also expressed their concerns about pharmacists performing some of the tasks that were mentioned. Dr. Isto felt that the tasks described were far removed from the practice of pharmacy that has been the norm.

099

Mr. Bohrer stated that many states are already doing this and the process has been successful. He emphasized that any task authorized would be performed under the authority of a licensed practitioner.

The board asked Dr. Nakamura to speak on these issues. Dr. Nakamura, Director, Division of Public Health, agreed that he did not really see a need for the proposed pharmacy regulations for the types of medications and screenings that were being discussed. He agreed this could potentially fragment the total care of the individual.

197

Dr. Nakamura addressed separately the issue of pharmacists dispensing emergency contraception. He spoke as a public health professional, as a pediatrician, and as an expert in public health. His comments follow:

Public health is focused on the prevention or amelioration of negative health consequences. This is in significant contrast to medical care that is focused on the treatment of adverse health conditions. Those in public health have a special interest in emergency contraception. Some of the adverse medical and social consequences that are prevented or ameliorated through the vigorous and innovative promotion of the EC service. He stated that 41 percent of the live births in Alaska are products of unintended pregnancies. The actual rate of unintended pregnancies is not known but the estimate is in the area of 60 percent.

A limited list of the many negative, social and medical consequences that would be prevented through the increased availability of emergency contraception includes: unintended pregnancies resulting from rape (Alaska has the highest rate of sexual assault in the U.S.); increased rate of adverse outcomes of pregnancy related to unintended pregnancies includes later prenatal care, lower birth rates, higher substance abuse rates, and infants with increased risks of being victims of abuse and neglect; the numbers of abortions will be significantly reduced. This is a critical point for many—the numbers of unintended pregnancies characterized by medical complications, psychological adversities, and social and economic unpreparedness will be reduced. Some projects have estimated that abortions can be reduced by 50 percent with increased availability of emergency contraception.

242

Dr. Nakamura requested the board's support in increasing the availability of emergency contraception services. Some of the measures that could be supported would be to consider legislation that would increase availability of EC through medical insurance, support the exploration of methods for increasing the availability of EC including advanced distribution of prescriptions from allied health professionals, increasing advertising of services, providers, and clients. In this case, this would give pharmacists the ability to respond to the very urgent need for this service. Reality has demonstrated that unless some of these services are immediately available and accessible, they do not get accessed.

259

In Dr. Nakamura's opinion, if this ability is granted to pharmacists, one requirement should be that they do make an immediate referral to the practicing physician. These patients should be referred for screening for sexually transmitted diseases and for psychological support. As a public health professional and as a pediatrician, he believes if the board could extend this authority for emergency contraception, it would support public health in Alaska.

275

Leaving emergency contraception aside, Ms. Means feels that the proposed regulations from the Board of Pharmacy would add to the complexity and confusion of the consumer.

300

Dr. Murphy distributed to the board a state Department of Epidemiology bulletin on unintended pregnancy. She clarified that emergency contraception medications are not to be confused with the abortion pill, RU-486. She also reinforced that other states are doing this collaboration successfully. She emphasized that the prescriptive authority lies with the physician, the pharmacist is dispensing the medication under a very detailed agreement.

339

Ms. Livsey spoke in favor of a more limited regulation permitting access to emergency contraception. She disagrees with the other board members; this is a voluntary relationship that physicians may choose to enter or not. The physician is the decision-maker in the relationship. There is nothing in the proposed regulation that pharmacists will be autonomously prescribing. The physician controls the communication and feedback. She supports the pharmacy regulation and also supports the emergency contraception collaboration.

Dr. Brownsberger and Cotten spoke against the board of pharmacy regulations. Dr. Cotten was particularly concerned about the fragmentation of care.

[Tape 6, Side A]

Dr. Isto believes that if the physician chooses to delegate the authority for a pharmacist to dispense emergency contraception, it would fall under 12 AAC 40.967 (8) that requires the licensee to insure that the person to whom the delegation is granted is properly educated and trained to perform. She does not support the delegation for other medications or procedures.

MOTION Upon a motion by ROTHROCK, seconded by BROWNSBERGER, and carried by a vote of six Yea votes (Rothrock, Means, Cotten, Brownsberger, Isto, and Olson) to one Nay vote (Livsey), it was **RESOLVED** that, acknowledging that emergency contraception is a separate issue, the board does not support the board of pharmacy's proposed regulation as outlined in the draft. 040

Ms. Abel confirmed with the board that it was her understanding that the medical board would support a very narrowly defined collaborative relationship between a physician and a pharmacist for the purpose of emergency contraception. The board agreed with that.

Dr. Isto reiterated that she would prefer the board of pharmacy draft a very narrowly defined regulation. She specified that this would be for medications that require emergency use that could not be easily or reliably obtained in other ways. She noted that emergency contraception is not the only medication that meets that criterion. 114

Dr. Murphy proposed that the board consider a requirement for a quality assurance component to any collaborative plan. She also offered to return to the board in a year with statistics to show the board how the program is working. 144

Dr. Murphy asked if she was authorized to proceed, and Ms. Abel read the regulation 12 AAC 40.967(8) that states that it would be unprofessional conduct to delegate a task to a person who is not properly educated and trained to perform the task. Therefore, if the person were properly educated and trained to perform the task, it would not be considered unprofessional conduct. 167

Dr. Isto reiterated that Dr. Murphy must make sure the person is qualified to do the task she is delegating. 190

AGENDA ITEM Reports, Investigations, MOAs 197

In the Matter of Ronald Brockman, DO 218

MOTION Upon a motion by LIVSEY, seconded by BROWNSBERGER, and carried without objection, it was **RESOLVED** that in accordance with AS 44.63.310(c)(2), the State Medical Board go into Executive Session for the purpose of discussing the matter of Ronald Brockman, DO. 244

Included in the executive session were board staff Matthews, Abel, Luker, and Stude. Also present was Matt Peterson, attorney for Dr. Brockman.

Off the record at 11:22 am; on the record at 11:39 am.

MOTION Upon a motion by BROWNSBERGER, seconded by ROTHROCK, and carried with six Yea votes (Isto, Means, Livsey, Brownsberger, Rothrock, and Cotten) and one abstaining member (Olson), it was **RESOLVED** to accept the memorandum of agreement with Ronald Brockman, DO. 265

Off the record at 11:40 am; on the record at 11:54 am.

AGENDA ITEM Regulations Review 271

The board reviewed and discussed the physician assistant regulation being proposed by the Alaska Academy of Physician Assistants. Tom Wilson spoke to the board about the regulation and the assessment form. He spoke about the need for the regulation change and clarified that the assessments would be face-to-face and could be done at either the physician or physician assistant's location. The location of the assessment will be included in the assessment form. The board specified that 10 percent of the PAs will be audited. Dr. Isto suggested that the random audit be done in the off year from renewals. Ms. Abel advised the board could require the audit of

The board expressed its thanks to Ms. Knuth and Dr. Worrall for meeting with them to discuss these issues.

The board recessed at 4:55 pm.

450

(Tape 5, Side A)

FRIDAY, JANUARY 19, 2001 - meet

The meeting was called to order at 9:10 am by chair Dr. Sarah Isto. Present were:

Board Members:	Martha T. Cotten, MD	Irvin A. Rothrock, MD
	Keith M. Brownsberger, MD	Sarah A. Isto, MD
Staff Members:	Joanie Studo	Colin Matthews
	Leslie Abel	
Visitors:	Ed Hall	Tom Wilson

Board members Sheila Means and Constance Livsey were absent.

AGENDA ITEM 10 Request for Board Opinion from Colleen Murphy, MD

The board reviewed the regulations proposed by the Board of Pharmacy. It was noted these are still in the regulations process. Mr. Matthews advised he was at the Board of Pharmacy meeting, and he informed the board of the discussion at that meeting. He noted the pharmacists want to do education programs for physicians but that he pointed out to the pharmacists that if they feel a prescription is inappropriate, they should contact the physician involved.

045

It was noted that Ms. Livsey arrived at the meeting.

A call was placed to Dr. Murphy. She did not answer but a message was left for her.

068

The board members reviewed the draft letter to Dr. Murphy and the protocol Dr. Murphy provided to the board for consideration.

MOTION Upon a motion by COTTEN, seconded by BROWNSBERGER, and carried without objection, it was

RESOLVED to finalize the draft letter to Dr. Murphy and send it to her. 097

AGENDA ITEM 11 Memorandum of Agreement

103

A new memorandum of agreement was distributed to the board members at the beginning of the meeting.

Ms. Means arrived at the meeting.

MOTION Upon a motion by LIVSEY, seconded by BROWNSBERGER, and carried without objection, it was

RESOLVED to go into executive session in accordance with AS 44.62.310(c)(2) for the purpose of discussing the matter of Raymond D. Hopson, MD.

112

Off the record at 9:19 am; returned on the record at 9:30 am.

MOTION Upon a motion by LIVSEY, seconded by BROWNSBERGER, and carried without objection, it was

RESOLVED to approve the memorandum of agreement with Dr. Hopson as written. 119

AGENDA ITEM 9 Reports

129

Jan 19, 2001 - cont.

Dr. Murphy called in to the meeting. Dr. Isto advised her that the board had addressed her issue and would be sending a letter to her immediately. 656

The board briefly discussed the pharmacy board's process for the collaborative plans. The medical board does not want to draft any specific regulations to address this process, nor do they want to review every plan that is written. If there is a complaint that is received by the medical board, the board will ask to see the plan, but unless that happens, they do not want to see the plans. It was the position of the board members that it is the pharmacy board's responsibility to insure the regulations are followed. Dr. Isto suggested a form letter that directs any inquiring physician to the appropriate regulation (the unprofessional conduct language).

[Tape 5, Start]

Returning to the matter of the courtesy license regulations, Dr. Isto summarized that the plan is to repeal the entire courtesy license regulations and redraft. The courtesy license is a special purpose license that is limited in scope and duration. The board discussed the examples offered by staff. If physicians come to Alaska on a regular or recurring basis, they should obtain a full, unrestricted license. There are other situations where physicians come up only once or twice a year, not always the same physicians, like the Shriners' physicians. 037

Approved by the board for the courtesy license are:

- 1 Physicians who come to the state for the purpose of a specialty clinic where there is no fee or remuneration paid by the patients for the service (e.g., the Shriners' physicians).
- 2 Out-of-state sports team physicians who accompany their team to the state for the duration of the team's presence in Alaska for the sporting activity and whose practice is restricted to care of the team and support staff personnel associated with the event.
- 3 Physicians who are formally contracted by state offices to conduct specialty clinics for the duration of the clinics.
- 4 Physicians who come to the state in response to a disaster, other than a federally declared natural disaster, for a duration not to exceed ninety (90) days. "Disaster" to be defined in the regulation with the assistance of Matt Anderson, EMS office.
- 5 Physicians who come to the state accompanying their employer/patient who may be licensed under this regulation for the duration of the travel only and practice restricted to that patient only.

The board determined that the minimum qualifications for such courtesy licenses will include:

- 1 Active license in good standing (no disciplinary sanctions or restrictions) in state of residence, not under investigation.
- 2 Board certification in an ABMS board specialty
- 3 Submit application and fees
- 4 Description of proposed practice including location, duration, patient population to be seen, etc.
- 5 ISMB Board Action Data Bank clearance report

The staff will write the application documents to parallel other applications. The board agreed that a definition of "courtesy license" should be written in the regulation including language that clearly states the exclusions: for the use of locum tenens coverage or to provide a physician to a community that does not have medical coverage. It must be clearly stated that this category of license is not a temporary license nor is it for employment try-outs. It is a limited purpose license for very specific circumstances. The board also wishes to include a definition for "disaster" in the regulation. Matt Anderson, EMS Training Coordinator, joined the meeting and advised he will assist in creating a definition of "disaster" for this regulation. The board would like the staff to bring this matter back to the April board meeting with proposed language. 279

MOTION Upon a motion by COTTEN, seconded by LIVSEY, and carried without objection, it was **RESOLVED** to direct staff to draft courtesy license regulations as discussed and have a draft available for the meeting in April. 287

It noted that Dr. Rothrock was not present for the vote.

FISCAL NOTE

STATE OF ALASKA
2003 LEGISLATIVE SESSION

Fiscal Note Number: _____
 Bill Version: SB 138
 () Publish Date: _____

Revision Date/Time (Note if correction): _____ Dept. Affected: DCED
 Title Pharmacist/Doctor Collaborative Protocols BRU Occupational Licensing (117)
 Component Occupational Licensing
 Sponsor Senator Dyson
 Requester Senate Health Education & Social Services Component No. 2360

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES ()	0.0	0.0	0.0	0.0	0.0	0.0
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other (Specify Type-Do not abbreviate)						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2003) cost: 0.0
 Mark this box (X) if funding for this bill is included in the Governor's FY 2004 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: (Attach a separate page if necessary)

SB 138 prohibits the Board of Pharmacy from adopting regulations allowing pharmacists to exercise collaborative practice authority; and anuls pharmacy regulation 12 AAC 52.240. New funds are not required to implement this bill.

Prepared by: Jennifer Strickler, Administrative Manager Phone 907-465-2144
 Division: Occupational Licensing Date/Time 4/14/03 3:45 PM
 Approved by: Edgar Blatchford, Commissioner Date 4/14/2003
 Agency: Department of Community & Economic Development

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

April 11, 2003

Honorable Fred Dyson
State of Alaska
Senate
Chair, Senate Health, Education and Social Services
State Capitol, Room 121
Juneau, AK 99801

Re: SB 138 – Collaborative Practice Authority by a Pharmacist; Annul 12 AAC 52.240

Dear Senator Dyson:

The Alaska State Medical Association (ASMA) represents Alaska's patients and the physicians who care for them. Thank you for the opportunity to testify on SB 138.

ASMA supports the passage of SB 138. SB 138 annuls a regulation, 12 AAC 52.240, which allows a pharmacist to either initiate or modify a drug therapy as long as a collaborative agreement and written protocol is entered into with a practitioner who has the authority to prescribe drugs. Those statutorily authorized practitioners are physicians, dentists, physician assistants, and nurse practitioners. 12 AAC 52.240 was adopted by the Board of Pharmacy and covers any drug able to be prescribed.

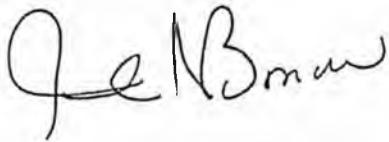
ASMA provided written testimony in opposition to the adoption of this regulation (see attached written comments dated December 13, 2000). ASMA continues to oppose these regulations for among the following reasons:

1. The Board of Pharmacy does not have sufficient statutory authority to adopt such a regulation and to reach beyond its regulatory scope to other regulated professions (e.g. physicians);
2. A physician would jeopardize her/his license by entering into such an agreement with a pharmacist. A physician cannot delegate duties to a person not appropriately licensed to perform those duties;
3. Under such arrangements, it is possible for a patient to never see a physician, but yet receive a prescription drug; and
4. 12 AAC 52.240 does not enhance the already good standard of care in Alaska.

ASMA is very concerned about the potential for harm to patients. The level of concern is such that ASMA's Board of Trustees has been directed by its policy making body, the House of Delegates, to explore legal as well as other available remedies, such as SB 138. Circumstances may exist involving an ongoing patient/physician relationship when such arrangements might work. However, such circumstances must be provided for in laws enacted by the Legislature and not by inappropriate regulatory fiat.

Attached is a document that outlines legal considerations, policy considerations, and conclusions, which elaborate on this issue.

Sincerely,

A handwritten signature in cursive script that reads "Jeanne Bonar". The signature is written in black ink and is positioned above the typed name.

By: Jeanne Bonar, MD
President

For: Alaska State Medical Association

SB-138

9621 Arlene Drive
Anchorage, AK 99502-1636
907-561-0005
Fax: 907-563-9140

11 April, 2003

Honorable Con Bunde
State of Alaska
Senate
Chair, Senate Labor and Commerce Committee
Juneau, AK 99801

Transmitted by Fax;
907-465-3871

RE: SB138 - Collaborative Practice Authority by a Pharmacist; Annul 12 AAC 52.240

Dear Honorable Bunde:

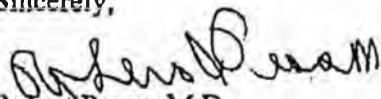
The Alaska Society of Anesthesiologists supports the passage of SB 138. SB 138 annuls a regulation which allows a pharmacist to either initiate or modify a drug therapy as long as a collaborative agreement and a written protocol is entered into with a practitioner who has the authority to prescribe drugs. Those statutorily authorized practitioners are physicians, dentists, physician assistants, and nurse practitioners. 12 AAC 52.240 was adopted by the Board of Pharmacy and covers any drug.

These regulations need to be annulled because the Board of Pharmacy exceeded its authority to act in a manner affecting other regulated professions. The regulation that they passed fails to support the current standard of good patient care. The regulation allows a patient to receive prescription medications without ever seeing a physician.

We are very concerned about the risks of substantial harm that this regulation represents to the patients of Alaska. Absent a physician caring for these patients with full knowledge of their medical history, co-morbidities, allergies, and family medical histories, the risks associated with the medical decisions associated with prescribing and altering therapies are great. The current regulation imposed on the practices of medicine by the Pharmacy Board fails to address those risks.

I urge you to aggressively support SB 138.

Sincerely,


Robert Pease, M.D.

President, Alaska Society of Anesthesiologists

CC: Senator Fred Dyson -- Fax 907-465-4587

**Anchorage
Society**

Medical

341 W. Tudor Rd.
Suite 101
Anchorage, AK
99503-6639

Phone (907) 562-1567
FAX (907) 561-7464

Honorable Fred Dyson
State Senate
Alaska State Capitol, Room 121
Juneau, AK 99801

Re. SB 138

Dear Senator Dyson,

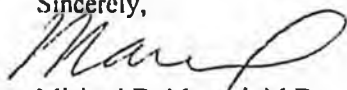
As President of the Anchorage Medical Society, I am writing on behalf of the organization in support of SB 138.

If one overlooks the *lack of statutory authority* under which the Pharmacy Board operated and the fact that they have *usurped the authority of the State Medical Board*, the most significant feature of the existing regulation concerns patient treatment and the standard of medical care in Alaska. Unless this regulation is reversed by passage of SB 138 the *potential to eliminate* patient-physician consultation and direct patient examination and evaluation will be recognized. The seamless oversight of the patient's entire medical history and condition by a trained professional is essential to the delivery of the highest level of medical care. Pharmacists, although important members of the treatment team, have not received the necessary education and training to make the decisions needed to direct patient care. Maintaining Alaska's existing high quality of medical care should be the goal of all health care professionals and the primary reason to pass SB 138.

Other issues regarding the availability of specific medications or the rules governing the role of pharmacists within the hospital environment can and should be addressed. These issues should be presented to the Legislature for full review and consideration rather than mandated by any regulatory board.

Thank you for your time and consideration in this matter.

Sincerely,



Michael D. Manuel, M.D.
President, Anchorage Medical Society

Alaska Physicians & Surgeons, Inc.

412C Laurel Street, Suite 206

Anchorage, Alaska 99508

Phone: 907-561-7705 Fax: 907-561-7704

E-mail: akphys@alaska.net

Website: www.apsdoctors.org

April 9, 2003

Honorable Fred Dyson
State of Alaska Senate
State Capitol – Room 121
Juneau, Alaska 99801

Dear Senator Dyson:

Alaska Physicians & Surgeons is in favor of annulling Regulation 12AAC 52.240, adopted by the Board of Pharmacy primarily from a patient care issue. The regulation has done nothing to enhance the current good standard of care provided to patients by the Alaska medical community. It specifically creates a situation where a patient may receive any type of medication without seeing a physician or a medical care provider licensed to prescribe. This could result in patient harm.

Secondly, it is difficult to understand where the statutory authority to adopt this regulation came from.

Alaska Physicians & Surgeons is very supportive of Senate Bill 138, and is concerned for patient safety until this is passed.

Sincerely,



Michael Norman, MD
President/Chairman of Board
Alaska Physicians & Surgeons

SB-136

MICHAEL B. ARMSTRONG, M.D.
Diplomate American Board of Internal Medicine
Subspecialty of Rheumatology
2841 DeBarr Rd., Suite 44
Anchorage, Alaska 99508
Telephone: (907) 277-1375
Fax: (907) 277-1376

April 11/02

Senator Jim Oyson.
Alaska State Legislature.

Re: SB 138.

I urge you to support
this measure to annual
prescriptive authority for
pharmacists. Only physicians
& clinical practitioners
should have this authority.

Michael Armstrong

Alaska State Hospital & Nursing Home Association

We're helping people care for people!

April 15, 2003

Senator Fred Dyson
Alaska State Legislature
State Capitol Building, Room 121
Juneau AK 99801-1182

Dear Senator Dyson:

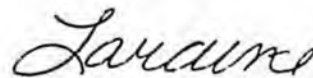
I am writing in relation to Senate Bill No. 138, annulling a regulation relating to the use of protocols.

Our hospitals have been using protocols for years. Use of protocols allows a more efficient and effective operation within the hospital as physicians and pharmacists alike know what is expected of them. Any changes in this area of medical practices will cause problems on both pharmacy and physician employees.

I am asking you to hold SB 138 until the medical association and pharmacy board have time to get together and cooperatively reach agreement on this issue. As so often happens, we try to fix one "problem" only to create others. I believe this is a true case of the "rotten apple" syndrome.

ASHNHA is an organization of hospitals and nursing homes. As such we lobby for the combined interests of our members. Holding SB 138 is in the best interest of our members.

Sincerely yours,



Laraine L. Derr
President/CEO

The logo for the National Association of Chain Drug Stores (NACDS) features the acronym "NACDS" in a bold, serif font, centered within a dark rectangular box with horizontal lines above and below the text.

NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

April 15, 2003

The Honorable Fred Dyson
Honorable Members of the Senate Health, Education and Social Services Committee
Alaska State Senate
State Capitol, Room 121
Juneau, AK 99801-1182

RE: Senate Bill 138 – Collaborative Practice Authority Repeal

Dear Chair Dyson and Members of the Committee,

On behalf of the Alaska members of the National Association of Chain Drug Stores, I would like to voice my strong opposition to the repeal of the Board of Pharmacy Regulation that allows pharmacists and prescribers to **voluntarily** enter into written collaborative arrangements that directly benefit the citizens of Alaska. NACDS members in Alaska include Costco, Kmart, Safeway (Carr's) and Wal-Mart and operate just over half of the 83 community pharmacies located in Alaska. In addition, they employ over 5,300 full and part-time employees and pay over \$4.6 million in taxes to the state.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

I am surprised that in a State such as Alaska, with boroughs and villages spread out across the state that legislation would be introduced that could severely limit access to state residents in remote and rural areas. Collaborative agreements enacted in states across the country allow prescribers and pharmacists to better manage a patient's care and ensure healthy outcomes. These are all done through written protocols and are generally patient specific. States that allow some form of collaborative practice agreements include: Arizona, Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington and Wyoming.

Chain community pharmacies do not believe that pharmacists should be given prescribing authority independent of physicians. However, in specific instances, consultation with a pharmacist is a safe, convenient, and more cost-effective way of addressing a drug therapy problem. Consider these examples:

Example 1: A patient taking penicillin comes in or calls a pharmacy reporting he has hives. Under a written agreement, a pharmacist may be authorized to change his medication to alleviate the allergic reaction.

Example 2: A patient complains of ringing in her ears and is taking anti-inflammatory medication. The pharmacist could, under the written agreement,

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

lower the dosage instructions for the patient to try and eliminate the side effect while still achieving the desired results.

Example 3: A patient on blood pressure medication complains of dizziness and fainting. Under a written agreement, a pharmacist could adjust the dosage of his medication to improve blood pressure and alleviate the unwanted effects of the medication.

Under the terms of collaborative practice agreements, the pharmacist would make the patient's physician aware of any change in drug therapy.

Collaborative practice agreements improve patient care in a variety of ways. Studies have shown that up to one-half of all patients do not completely comply with their prescription drug therapy. Pharmacy services administered by pharmacists in chain and independent pharmacies have been proven to improve compliance and prevent unnecessary hospitalizations caused by drug misuse. Collaborative practice agreements are another mechanism to increase the opportunities for pharmacists to contribute their expertise to drug therapies.

Collaborative practice agreements increase patient accessibility to necessary services and also strengthen the pharmacist-physician relationship, ensuring that patients receive the most appropriate and comprehensive drug therapy.

Community pharmacists **ARE NOT** seeking independent prescribing authority. Collaborative practice agreements would only allow pharmacists to modify, continue or discontinue a patient's prescription drug therapy under **written** protocol after a physician's diagnosis.

Community pharmacists **ARE NOT** seeking to require physicians to participate in collaborative practice agreements. In order to function more efficiently in a marketplace ruled by capitation, physicians may seek to share some of their traditional responsibilities with their professional colleagues. Collaborative practice agreements will allow physicians and pharmacist to **voluntarily** engage in these arrangements.

Community pharmacists **ARE NOT** seeking to require patients to engage in any relationship with which they are uncomfortable. If patients do not want pharmacists modifying their drug therapy or wish to maintain their relationship with pharmacists who are not covered by an arrangement, they are under no obligation to participate in a collaborative practice agreement.

These agreements, that through legislation you are proposing to "outlaw", allow for the voluntary participation of the physician, the patient and the pharmacist. For any pharmacist, physician or patient not comfortable with an agreement, they can simply

choose to not participate. For those that see the benefit of working in collaboration together, this gives them the opportunity to pursue a working relationship of this nature.

In the State of Washington, the medical community has been working collaboratively with the pharmacy community for over 20 years. The agreements in Washington exist in both the retail and the institutional setting. Physicians, pharmacists and patients are pleased with the positive health outcomes in which these agreements have resulted. In the retail setting pharmacists are able to administer vaccinations, participate in asthma, diabetes and heart disease state management programs, as well as initiating smoking cessation programs. All these are done through written protocols between a licensed physician and a licensed pharmacist.

I strongly encourage you to not undo what has been done, and not prohibit this practice in the State of Alaska.

Sincerely,



Lis Merten
Regional Director, State Government Affairs
924 Capitol Way South, Suite 216
Olympia, WA 98501
(360) 236-1246
lmerten@nacds.org

cc: Senator Lyda Green
Senator Gary Wilken
Senator Betty Davis
Senator Gretchen Guess



March 22, 2003

3200 Providence Drive
P.O. Box 196604
Anchorage, Alaska
99519-6604

Tel 907.562.2211

The Honorable Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, Alaska 99801-1182

MAR 28 2003

RE: Senate Bill 138 - Collaborative Practice Authority Repeal

Dear Senator Dyson:

On behalf of the Alaska Pharmacists' Association I am writing to urge you to withdraw Senate Bill 138 which would annul the State Board of Pharmacy Collaborative Practice Regulation (section 12 AAC 52.240). This regulation defines the *standards and scope of practice guidelines* for pharmacists who wish to work collaboratively with physicians in caring for patients, specifically by managing drug therapy *once a diagnosis is made*.

Collaborative practice agreements are voluntary on the part of a physician and include protocols developed jointly by the physician/s and pharmacist/s.

Collaborative practice between pharmacists and physicians is not a new concept. Collaborative Drug Therapy Management is addressed in legislation of 39 states, 33 with statutes or regulations, 7 via Medical Practice Acts or other rulings. Thirty-eight include institutions and 29 include community pharmacies.

Collaborative practice services are of great benefit to patients and physicians:

In community pharmacy settings and clinics, collaborative practice arrangements have resulted in a number of positive affects on patient outcomes, as demonstrated in several clinical studies. Patients managed by pharmacist's in an anticoagulation clinic had fewer emergency room visits, fewer hospitalizations and showed a total cost savings of \$1,621 per patient.¹ Community pharmacists conducting an asthma management clinic decreased hospitalizations by 77% and emergency room visits by 78%.² Pharm.acists providing asthma management services to two employers decreased cost, improved care and improved work absence rates.³ Pharmacists providing flu and pneumonia immunizations increased vaccination rates in high risk patients by 74%, with resultant cost savings from reductions in complications due to the infections.⁴ In addition to improvement in outcomes and cost savings, collaborative practice can quicken needed doses or drug adjustments, increase patients' adherence to therapeutic plans, reduce adverse drug reactions through early detection and improve access to the healthcare system.

In hospitals, physicians and pharmacists have been involved in collaborative practice agreements for more than 30 years in the areas of pain, anticoagulant, antibiotic and parenteral nutrition management and drug dosing in kidney impairment, to name a few. Pharmacists improve care of patients and leverage physicians numerous times daily in any one hospital.

Many of the services provided under the collaborative practice umbrella have developed due to the expertise of the pharmacist in those areas, recognition of that expertise by physicians, and their desire to

employ the most efficient approach to managing the therapy. *Annulling this regulation does not mean going back to the status quo (in hospitals) prior to its passage. An annulment may mean total elimination of these services.*

Annulling the regulation will also result in more telephone calls to physicians who have hospitalized patients, burdening already stretched pharmacists and physicians. Pharmacists would otherwise be screening orders written by physicians for the same service. In many cases pharmacists would have reason to call a physician with an alternative recommendation, need for clarification, etc., or write a note resulting in a delay of optimal therapy. More than 90% of these communications result in a change by the physician. Why impose unnecessary burden by eliminating collaborative practice agreements?

Innovation and creativity is required to improve care for patients with chronic conditions. Society is aging. Older adults require more medications and have more chronic diseases that complicate their use of medications. Frailties can interfere with taking medications. Medication use is growing (6.9% of healthcare expenditures in 1995 to 9% in 2000, \$121.8 billion). Use of alternative therapies that can influence traditional medications is widespread. Medication costs are increasing. Pharmacists are the 3rd largest healthcare provider group (RN 2.2 million, MD 598,000, RPh 200,000) and are at a point of easy access to the system. *Pharmacists are responsible for contributing jointly to improve care and control costs to the patient, community and state. We can do this most effectively through collaborative practice.*

The return on investment in pharmaceutical care services is great from the standpoints of drug costs and outcomes. The collaborative practice regulation may provide a foundation for future governmental reimbursement for such services. Financial support will allow pharmacists to more effectively serve as members of the healthcare team.

In Collaborative Practice, pharmacist activities may include:

- Assisting physicians in improving medication management and continuity of care (regular communication)
- Providing, initiating, modifying, continuing, discontinuing, and monitoring a patient's drug therapy
- Ordering, performing and interpreting medication-related lab tests
- Assessing patient response to therapy
- Counseling and educating a patient regarding medications
- Administering certain medications such as vaccines

The following examples illustrate the process and some benefits:

Warfarin Dosing Clinic: Warfarin is a medication used to prevent life-threatening blood clots. Dosing is very dependent on patient factors, diet and other medications. If dosed too low, the patient may experience a clot resulting in hospitalization or death; if too high, bleeding may occur and can be fatal. Lab tests must be checked regularly and doses adjusted frequently according to the protocol. A physician refers a patient to the pharmacist at the clinic and the dosing, lab checks and patient education are done by the pharmacist. There is regular reporting of a patient's status to the physician and documentation of patient visits in a medical record. Physicians are consulted for circumstances outlined in the protocol or when situations occur that are outside the protocol. Patients are not always compliant with appointments for their lab tests - a tight tracking mechanism ensures they are called with a reminder. Warfarin dosing clinics have provided a degree of oversight not usually attainable by physician offices and have

decreased the adverse events associated with over or under dosing. Pharmacists are excellent providers of this service as a result of their training in pharmacology, diet-drug interactions and drug-drug interactions. Visits to these clinics are less costly to the patient and provide regular contact with a patient on a high-risk drug. Oftentimes, other medical problems are noted during the visit and the patient is referred to the physician.

Aminoglycoside Dosing: Aminoglycosides are antibiotics used for serious infections, most often in the hospital. Successful treatment of an infection and avoidance of toxic drug effects depends on proper blood levels of the drugs. Physicians will write an order for a pharmacist to dose the antibiotic. The pharmacist orders the lab tests required for dosing and safe use, according to the Pharmacy and Therapeutics Committee guidelines, until the physician discontinues the medication. Special analytical calculations are sometimes required to determine the correct dosage. This service optimizes drug levels earlier, potentially speeding recovery, avoids toxicity and decreases the number of blood tests a patient must undergo, thereby decreasing cost of care.

In recent discussion between pharmacists and physicians regarding the Collaborative Practice Regulations, several concerns have been raised.

1. Pharmacists will be able to provide, initiate or discontinue medications autonomously: Per a collaborative practice agreement, the physician is requesting that a medication be initiated or discontinued according to the protocol. In the case of a clinic or community pharmacy, the protocol would be created by a physician and a pharmacist or group of pharmacists employed by the pharmacy. In the case of a hospital, the Pharmacy and Therapeutics Committee represents the medical staff and is the usual approval body for protocols applicable to inpatients. Protocols define type of patient, disease state, drug or drug category involved, what authority is authorized in each case and the steps to follow when making decisions. Some protocols may contain a decision algorithm to identify need.
2. The State Board of Pharmacy does not have the right to dictate physician delegation of prescribing: The regulation applies to *pharmacists* entering into agreements with physicians.
3. Physicians will not be aware of the patient's status: Protocols are required to identify the methods of documentation and communication with the physician. Decisions must be evaluated by the physician/s at least once every 3 months. In many cases, this occurs much more frequently; in the hospital, daily.
4. Pharmacists aren't qualified for drug therapy management: Pharmacists are the only healthcare professionals whose training primarily focuses on medication use. All pharmacists have had a minimum of 3 years of pharmacy education after 2 years of general college. Some previous grads and all current grads receive a clinical doctorate degree, Pharm.D., after a minimum of 4 years of pharmacy education, including:
 - Didactic coursework in disease states and evidence based therapeutics
 - Basic physical assessment
 - Experiential training in care planning (patient-specific drug choice, outcome goals, monitoring plans, dose adjustment, drug-drug and drug-disease interaction management) and collaboration with other disciplines
 - How to educate regarding medications
 - Philosophy of direct responsibility to the patient

Senator Fred Dyson

Page 4.

March 25, 2003

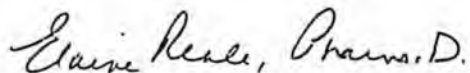
Pharmacists may also have completed general or specialty residencies or have received certification: National Institute for Standards in Pharmacist Credentialing (Asthma, DM, Anticoagulation, Lipid, etc.); Board of Pharmaceutical Specialties, (Pharmacotherapy, Nutrition, Oncology, Psychiatry)

Collaborative Practice Protocols must specify whether completion of additional training is required.

5. Pharmacists will compete with physicians for patients: Collaborative practice is not independent practice. Pharmacists wish to join in the restructuring of healthcare via a team approach using knowledge and skills that are complimentary to those of other disciplines.⁵

Please consider these points and the potential contribution of pharmacists in helping resolve our burgeoning healthcare problems. Surely this will lead you to a different point of view on the State Board of Pharmacy Collaborative Practice Regulation.

Sincerely Yours,



Elaine Reale, Pharm.D., Clinical Manager
Providence Alaska Medical Center
Member, Alaska Pharmacists' Association

Attachment

¹Comparison of an anticoagulation clinic with usual medical care. Anticoagulation control, patient outcomes and health care costs. Chiquette E, et.al. Arch Int Med 1998;158:1641-7.

²Developing and marketing a community pharmacy-based asthma management program. Rupp MT, et.al. J Amer Pharm Assoc; 1997 Nov-Dec;37(6):694-9.

³The Ashville Project. Pharm Times. Romaine Pierson Pub. Westbury:NY. Oct 1998.

⁴Community pharmacists as immunization advocates: a pharmacoepidemiologic experiment. Int J Pharm Pract Grabenstein JD. 1993;2:5-10.

⁵Quality Chasm Report, 2001 Institute of Medicine

Collaborative Drug Therapy Management

What is Collaborative Drug Therapy Management (CDTM)?

Pharmacists and physicians voluntarily enter into an agreement to jointly manage a patient's drug therapy via a predetermined protocol. Pharmacist activities may include:

- Assisting physicians in improving medication management and continuity of care (regular communication)
- Providing, initiating, modifying, continuing, discontinuing, and monitoring a patient's drug therapy
- Ordering, performing and interpreting medication-related lab tests
- Assessing patient response to therapy
- Counseling and educating a patient regarding medications
- Administering certain medications such as vaccines

Benefits

- Improves drug therapy outcomes
- Reduces delays in modifying drug regimens
- Increases patient adherence to therapeutic plans
- Reduces adverse drug reactions through early detection
- Reduces emergency department visits
- Improved access to the healthcare system

How are pharmacists prepared to do CDTM? Why pharmacists?

- The only healthcare professionals whose training primarily focuses on medication use.
- Clinical doctorate degree, Pharm.D., after a minimum of 4 years of pharmacy education including:
 - Didactic coursework in disease states and evidence based therapeutics
 - Basic physical assessment
 - Experiential training in care planning (patient-specific drug choice, outcome goals, monitoring plans, dose adjustment, drug-drug and drug-disease interaction management) and collaboration with other disciplines
 - How to educate regarding medications
 - Philosophy of direct responsibility to the patient
- General and specialty residencies - intensive experience in clinical application and collaboration
- Certification - National Institute for Standards in Pharmacist Credentialing (Asthma, DM, Anticoag, Lipid, etc.); Board of Pharmaceutical Specialties, (Pharmacotherapy, Nutrition, Oncology, Psych)
- 3rd largest healthcare provider group: (RN 2.2 million, MD 598,000, RPh 200,000); Point of easy access to system

Why is legislation necessary?

- Define scope of practice at State level
- Establish standards of practice
- Foundation for reimbursement to support service provision

National Statistics on CDTM

- 39 states have some form of CDTM (33 with statutes or regulations, 7 via Med Practice Acts or other rulings)
- 34 states include hospitals in addition to other types of facilities
- 29 states include community pharmacies
- 67% of 376 integrated health systems have pharmacists who routinely participate in ambulatory clinics for chronic diseases (ASHP 2001 survey)

Increasing Need for Medication-Related Services and Pharmacist Involvement

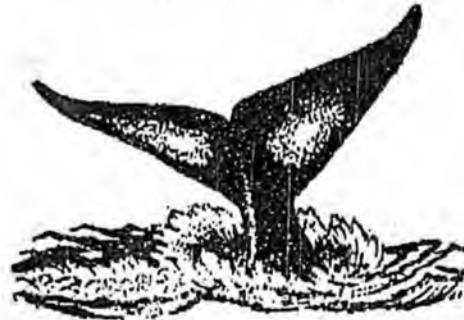
- Aging of society – Older adults require more medications and have more chronic diseases complicating their use of medications. Frailties can interfere with taking medications.
- Medication use is growing: 1995 6.9% of healthcare expenditures to 9% in 2000 (\$121.8 billion)
- Use of alternative therapies that can influence traditional medications is widespread
- Medication costs are increasing
- Shortages of other healthcare personnel

Supporting Concepts from National Medical Leadership

2001 Institute of Medicine Quality Chasm Report: The healthcare system must be restructured incorporating a team approach utilizing the combined efforts of a variety of healthcare providers with overlapping knowledge and skills; improve care for patients with chronic conditions via innovation and creativity. **American College of Physicians and American Society of Internal Medicine in 2002:** Endorsed the evidence based value of pharmacist contributions in hospital settings and recommended more rigorously investigating the value of pharmaceutical care services in the community. **"Interdisciplinary care requires common values, a common vision and an intuitive understanding of teamwork."** (Max Ray) **Inherent in teamwork is trust.**

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P.O BOX 709; Craig, AK 99921
(907) 826-5750/Fax: 826-5752



Honorable Senator Fred Dyson
Alaska State Senate

4 April 2003

Dear Senator Dyson,

I have just read over Pharmacy Board Regulation 12 AAC 52.240 relating to pharmacist collaborative practice authority. I would like to list some considerations to this regulation which come to my mind:

* This particular "type" of practice is currently being used extensively in the rural areas of Alaska by the Native health facilities. Health aids are initiating treatments and dispensing prescription medications to their patients based on a "flow chart" system used by Native health. Whether good or bad, the situation necessitates this practice. I have worked in pharmacies in 16 different rural areas in our state and know that this is a common practice. It seems to work relatively well based on the protocols.

* My wife and I have worked in Medical Missions in three different locations. There were always treatment protocols in place in all 3 of these places, similar to "collaborative practice agreements". They seemed to increase the level of timely patient care and reduce overall expenses at these mission hospitals.

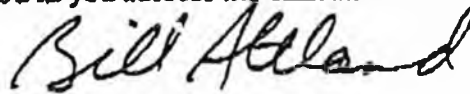
* We have worked in other states in the U.S. as pharmacists and this type of practice seems to be the standard of care for other locations in the U.S.

* We currently work in a rural, remote part of Alaska here on **Prince of Wales Island** - in southeast Alaska. We, as pharmacists, are often the most available health care personnel to the public. Folks have access to us when other medical providers are not immediately available. There are many small communities in Alaska which are similar to our situation.

* We have heard that the issue of emergency contraception is part of the reason for this practice now being an issue. It seems to me that other standing protocols between health professionals for these other disease states are much more important and should be considered as being retained before contemplating a discontinuation of the entire collaborative practice. Pharmacists (ourselves included) feel that there is a place for the continuation of collaborative practice agreements between physicians and pharmacists.

Hope this is of help. Thank you for your service to the State in the Alaska Senate. I will be praying for you as you address the difficult decisions unique to your position.

Sincerely,

A handwritten signature in cursive script that reads "Bill Atland". The signature is written in black ink and is positioned to the right of the word "Sincerely,".

Bill Atland, Registered Pharmacist



April 15, 2003

The Honorable Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, AK 99801-1182

RE: Senate Bill 138 – Collaborative Practice Authority Repeal

Dear Chair Dyson,

On behalf of Costco Wholesale and our Pharmacy locations in Alaska, I would like to voice my strong opposition to the repeal of the Board of Pharmacy Regulation that allows pharmacists and prescribers to voluntarily enter into written collaborative arrangements that directly benefit the citizens of Alaska.

I am surprised that in a State such as Alaska, with boroughs and villages spread out across the state that legislation would be introduced that could severely limit access to state residents in remote and rural areas. Collaborative agreements enacted in states across the country allow prescribers and pharmacists to better manage a patient's care and ensure healthy outcomes. These are all done through written protocols and are generally patient specific. States that allow some form of collaborative practice agreements include: Arizona, Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington and Wyoming.

Costco Pharmacy does not believe that pharmacists should be given prescribing authority independent of physicians. However, in specific instances, consultation with a pharmacist is a safe, convenient, and more cost-effective way of addressing a drug therapy problem. Consider these examples:

Example 1: A patient taking penicillin comes in or calls a pharmacy reporting he has hives. Under a written agreement, a pharmacist may be authorized to change his medication to alleviate the allergic reaction.

Example 2: A patient complains of ringing in her ears and is taking anti-inflammatory medication. The pharmacist could, under the written agreement, lower the dosage instructions for the patient to try and eliminate the side effect while still achieving the desired results.

Example 3: A patient on blood pressure medication complains of dizziness and fainting. Under a written agreement, a pharmacist could adjust the dosage of his medication to improve blood pressure and alleviate the unwanted effects of the medication.

Under the terms of collaborative practice agreements, the pharmacist would make the patient's physician aware of any change in drug therapy.

Collaborative practice agreements improve patient care in a variety of ways. Studies have shown that up to one-half of all patients do not completely comply with their prescription drug therapy. Pharmacy services

administered by pharmacists in chain and independent pharmacies have been proven to improve compliance and prevent unnecessary hospitalizations caused by drug misuse. Collaborative practice agreements are another mechanism to increase the opportunities for pharmacists to contribute their expertise to drug therapies.

Collaborative practice agreements increase patient accessibility to necessary services and also strengthen the pharmacist-physician relationship, ensuring that patients receive the most appropriate and comprehensive drug therapy.

Costco pharmacists **ARE NOT** seeking independent prescribing authority. Collaborative practice agreements would only allow pharmacists to modify, continue or discontinue a patient's prescription drug therapy under written protocol after a physician's diagnosis.

Costco pharmacists **ARE NOT** seeking to require physicians to participate in collaborative practice agreements. In order to function more efficiently in a marketplace rules by capitation, physicians may seek to share some of their traditional responsibilities with their professional colleagues. Collaborative practice agreements will allow physicians and pharmacist to **voluntarily** engage in these arrangements.

Costco pharmacists **ARE NOT** seeking to require patients to engage in any relationship with which they are uncomfortable. If patients do not want pharmacists modifying their drug therapy or wish to maintain their relationship with pharmacists who are not covered by an arrangement, they are under no obligation to participate in a collaborative practice agreement.

These agreements, that through legislation you are proposing to "outlaw", allow for the voluntary participation of the physician, the patient and the pharmacist. For any pharmacist, physician or patient not comfortable with an agreement, they can simply choose to not participate. For those that see the benefit of working in collaboration together, this gives them the opportunity to pursue a working relationship of this nature.

In our home State of Washington, the medical community has been working collaboratively with the pharmacy community for over 20 years. The agreements in Washington exist in both the retail and the institutional setting. Physicians, pharmacists and patients are pleased with the positive health outcomes in which these agreements have resulted. In the retail setting pharmacists are able to administer vaccinations, participate in asthma, diabetes and heart disease state management programs, as well as initiating smoking cessation programs. All these are done through written protocols between a licensed physician and a licensed pharmacist.

I strongly encourage you to not undo what has been done, and not prohibit this practice in the State of Alaska.

Sincerely,



Michael Mastromonica, R.Ph.
Assistant GMM, Pharmacy



File SB-138

April 7, 2003

Senator Fred Dyson
State Capitol—Room 121
Juneau, AK 99801-1182

Re: SB 138, Collaborative Practice

Dear Senator Dyson:

Our organization, the Academy of Managed Care Pharmacy (AMCP), rarely takes positions on state legislative proposals. We feel compelled to do so in this instance because of **our opposition to Senate Bill 138**. SB 138 would annul an already existing regulation permitting collaborative practice agreements between pharmacists and prescribers, whereby pharmacists may initiate or modify drug therapy “in accordance with a written protocol established and approved...by a practitioner authorized to prescribe drugs.” If enacted, SB 138 would seriously incapacitate our pharmacist members in their ability to provide appropriate drug therapy management within the State of Alaska, and we believe that would be to the detriment of the citizens of your state.

The Academy of Managed Care Pharmacy is a professional association of pharmacists and associates who serve patients and the public by the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and service to the more than 200 million Americans served by managed care.

AMCP strongly supports the concept of collaborative practice agreements—which are currently allowed in 34 states, including Alaska—whereby a pharmacist can initiate, modify, or continue drug therapy in accordance with written guidelines or protocols previously established and approved by a practitioner authorized to prescribe medications. The purpose of a collaborative practice agreement is to improve the general public health by extending higher quality health care services to more patients than is currently available.

Examples of the specific services pharmacists can provide under a collaborative practice agreement include:

- Monitoring and evaluating the patient’s response to therapy and providing recommendations regarding necessary changes
- Managing and monitoring drug therapy in patients receiving treatment for cancer or chronic conditions such as asthma and diabetes
- Consulting with patients and their families on proper use of medications

President
C.E. (Gone) Reeder, RPh, PhD
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College of Pharmacy
Columbia, SC

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Director
Debbie Stern, RPh
Rxparts
Irvine, CA

Executive Director
Judith A. Cahill, CEBS
AMCP
Alexandria, VA

100 North Pitt Street
Suite 400
Alexandria, VA 22314

703 683 8416
800 827 2627
Fax 703 683 8417

- Conducting wellness and disease prevention programs to improve public health
- Overseeing medication use in a variety of settings: home care settings, hospitals, ambulatory care, nursing homes and other long-term care facilities, clinics, and intensive care units.

Collaborative practice agreements are particularly useful in areas where health care services are widely dispersed, because they afford patients access to pharmacists, when other health care professionals may not be as easily accessible.

Working closely and collaboratively with physicians, the pharmacist can serve as a trusted counselor to help streamline drug therapies prescribed by a number of specialists and match effective therapies with a patient's unique needs. The pharmacist can also play a vital role in follow-up care, by monitoring patient response and advising physicians on changes in dosage, medicine, or delivery method. By incorporating the pharmaceutical care process into the patient's health care plan, the health care team assumes responsibility for ensuring that positive therapeutic and quality of life outcomes are achieved.

We strongly urge you to withdraw SB 138 from consideration.

Sincerely,



William Hermelin
Director of Government Relations and General Counsel

Enclosures:

Where We Stand: Collaborative Practice Agreements
Where We Stand: Compensation for Pharmaceutical Care Services
Concepts in Managed Care Pharmacy: Pharmaceutical Care

CC:

Senate Labor and Commerce Committee: Senators Bunde, Seekins, Stevens, Davis, French

Senate Judiciary Committee: Senators Seekins, Ogan, Therriault, Ellis, French



AMERICAN ASSOCIATION
OF COLLEGES OF PHARMACY

WILLIAM G. LANG IV, MPH
DIRECTOR-GOVERNMENT RELATIONS

1426 Prince Street • Alexandria, Virginia 22314-2841 • (703) 739-2330 x1038
FAX: (703) 836-8982 • wlang@aacp.org



JASON SB-138

AMERICAN ASSOCIATION
OF COLLEGES OF PHARMACY

April 1, 2003

The Honorable Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, Alaska 99801-1182

Dear Senator Dyson:

I am writing to you today to ask you to reconsider your intention to repeal Alaska's pharmacist/physician collaborative practice act, (12AAC 52.240).

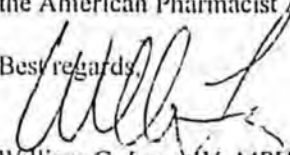
Collaborative practice acts are particularly effective in rural and frontier states like Alaska, where access to health care services can be severely limited. Collaborative practice acts, including Alaska's, do not allow pharmacists to prescribe drugs. A pharmacist's actions are at all times determined by the contract developed and signed with the authorized prescriber. A pharmacist acting outside this contract is subject to disciplinary action by the Alaska State Board of Pharmacy.

The American Association of Colleges of Pharmacy (AACCP) is a member of the Alliance for Pharmaceutical Care (APC). This coalition of pharmacy organizations annually hosts a large exhibit during the National Conference of State Legislators annual meeting. The exhibit is a well-attended event that demonstrates the clinical capabilities of today's pharmacist. State legislators see first hand why collaborative practice laws are important mechanisms that improve patient health outcomes. A recent study in Minnesota concludes, "The results of this study suggest that decisions made by pharmaceutical care practitioners, working in collaboration with physicians and other care givers to provide drug therapy management services, are clinically credible...."¹ The Alliance would certainly welcome the opportunity to demonstrate to you the value of pharmaceutical care services should you attend the NCSL meeting this year in San Francisco.

Since there is not a school of pharmacy in Alaska, I cannot invite you to visit and see the in-depth knowledge pharmacy students are instilled with regarding pharmaceuticals and their impact on humans. The pharmacist as a clinical health care professional is gaining increased recognition throughout our nation's health care delivery system. The power, number, and increased use of pharmaceuticals make it imperative that physicians and other authorized prescribers have ready access to a pharmacist. Collaborative practice acts make this a reality.

Should you need additional information or wish to discuss our request, please do not hesitate to give me a call. You can also find additional information regarding the Alliance for Pharmaceutical Care and collaborative practice through the website of the American Pharmacist Association at www.aphanet.org.

Best regards,


William G. Lang IV, MPH
Director of Government Affairs

1426 Prince Street • Alexandria, Virginia 22314-2841 • (703) 739-2330 • Fax (703) 836-8982 • www.aacp.org

¹ Isetts, B, et al. Quality Assessment of a Collaborative Approach for Decreasing Drug-Related Morbidity and Achieving Therapeutic Goals. *Archives of Internal Medicine* 2002.



Anchorage Pioneers' Home

Nancy O. Davis 907 583-7880

JASW
SB-138

p.03

ROBERT ALBERTSON
CS, CGP, FASCP
Chief Pharmacist

State of Alaska
Department of Administration
Alaska Longevity Program Division
E-mail: robert_albertson@admin.state.ak.us

Ph: (907) 343-7294
Fax: (907) 343-7270
923 W. 11th Avenue
Anchorage, AK 99501

ii

March 27, 2003

RE: SB 138, Collaborative Practice Authority Repeal

Dear Senator Dyson,

I must ask you to reconsider your bill SB 138. This bill will undermine the cooperation and collaboration that physicians and pharmacists have practiced for decades. Pharmacists have worked with physicians, nurses, and patients to provide smooth integration of care, to decrease over all healthcare costs, and improve patient outcomes.

The Board of Pharmacy regulations concerning collaborative practice were issued on the request of the profession and other health care professionals *to help formalize and regulate a standard of practice* that has been practiced in hospitals and community setting for years. It does not issue prescriptive authority to pharmacists.

Pharmacists are extensively qualified, due to our length and depth of training, to implement a physician directed protocol. As laid out in the collaborative practice regulations, these interventions are shown to improve patient care. Many studies have shown that by improving patient health through collaborative practice -type protocols, the overall health dollars spent is drastically reduced. In addition these types of interventions help free the already limited time of busy physicians.

To repeal this regulation will not bring the profession of pharmacy back to the time just prior to the enactment of these regulations, but will undo the last 30 years of pharmaceutical advancement in community and hospital practice.

It is in the interest of patient's well being that I implore you to withdraw this bill, SB 138.

Sincerely,


pharmacist

Note: not one lawsuit has been filed in WA state against CDTP.

MEMORANDUM

Communication received 9/17/03

They TO: have General Medical Staff of PAMC had protocols FROM: Peter B. Adams, M.D. in place Chief of Staff, Providence Alaska Medical Center since DATE: 1979. March 11, 2003

PBA.

RE: Pharmacy Collaborative Practice Act & Compliance at PAMC

At the February Medical Executive Committee meeting, Dr. Bundtzen, Chair of the Pharmacy & Therapeutics (P&T) Committee, informed the members that in 2002 the Board of Pharmacy enacted Collaborative Practice regulations. Collaborative Practice is an agreement between a physician and pharmacist(s) that permits the pharmacist(s) to manage specific drug therapies in accordance with a written protocol. These protocols must meet specific requirements. While the language of the legislation is geared toward retail pharmacy practice, the board did decide that hospitals needed to submit protocols that had been approved by the organization's Pharmacy and Therapeutics committee. Any physician on a hospital's medical staff could activate these protocols by writing an order for a specific patient. An example would be a request for pharmacy to dose a specific aminoglycoside by protocol.

Jim Moran, Director of PAMC Pharmacy, requested that the Medical Executive Committee allow Dr. Bundtzen, as the P&T Committee Chair, to sign a protocol representing the Medical Staff's ability to participate in collaborative practice with pharmacists at PAMC. A discussion ensued regarding concerns of the Alaska State Medical Association related to inclusion of physician prescribing authority delegation in the regulation. Members agreed that Dr. Bundtzen sign the protocol so that Providence Pharmacy may be in compliance with the law until the issues in question are worked through.

(Note: in-risk medical sys., heparin, lidocaine, gentamicin, coumadin, total parenteral nutrition)

At the February 13, 2003 State Board of Pharmacy meeting, the following wording was approved for submission as an addition to the current regulation: "Nothing in this section (regarding collaborative practice) shall be construed to prohibit pharmacists practicing in an institutional facility from participating in drug therapy protocols and guidelines approved by the Pharmacy and Therapeutics Committee or other medical staff governing bodies of the institution. Records will be maintained and available to the board upon request." This exempts hospitals whose protocols are approved by their P&T Committee from submitting protocols to the Pharmacy Board for approval. Should this addition proceed successfully through legislative channels in the next year, protocols for hospitals will not require State Board of Pharmacy approval if they already have been approved by P&T.

Others

Providence Department of Pharmaceutical Care Services is now in full compliance with the regulation, allowing our current and preexisting practices of collaboration with physicians' in-patient care to continue.

SB 138

Subject: FW: Threat to Coumadin Clinic

Date: Mon, 14 Apr 2003 12:54:05 -0800

From: "Snyder, Jean" <jsnyder1@provak.org>

To: "Senator_Fred_Dyson@legis.state.ak.us" <Senator_Fred_Dyson@legis.state.ak.us>

>
> I have been made aware today of SB 138 that would repeal the provision in
> the current statutes that allows for collaborative relationships between
> physicians and pharmacist that permits the pharmacist to initiate or modify
> drugs in accordance with a written protocol approved by the pharmacy board
> and the person with the prescriptive authority. Please reconsider. If
> this bill passes our coumadin clinic would disappear, which is a
> tremendous service to our patients. It would also prevent emergency
> contraception resulting in an increase in unwanted pregnancies and the
> resultant abortions.
>
> Thanks.

Jean Snyder MD

This message is intended for the sole use of the individual to whom it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the addressee you are hereby notified that you may not use, copy, disclose, or distribute to anyone the message or any information contained in the message. If you have received this message in error, please immediately advise the sender by reply email and delete this message.

Subject: SB 138

Date: Mon, 7 Apr 2003 17:29:51 -0800

From: "Schwartz, John" <jschwart@provak.org>

To: "Senator_Fred_Dyson@legis.state.ak.us" <Senator_Fred_Dyson@legis.state.ak.us>

Dear Senator Dyson,

I am writing to urge you to stop further consideration of SB 138 relating to collaborative agreements between pharmacists and physicians. I have been in the practice of medicine in Alaska for 23 years and I am board certified in internal medicine, family medicine and geriatric medicine and am currently a faculty member of the Alaska Family Medicine Residency that trains family physicians for practice in Alaska. Our patients are cared for by over 30 physicians and mid-level practitioners and we are busy with the job of caring for an increasing number of older Alaskans who are unable to be seen by the private community due to the access issues caused by a failing medicare program. We have had a collaborative relationship with the pharmacists at Providence Hospital to manage patients on a blood thinner called coumadin that has worked very well over the last couple of years. This program has increased the safety for our patients in taking a potentially dangerous but beneficial medicine and is a good example of what could not take place in the future if your bill is adopted. I would be happy to discuss this issue with you or testify at a committee meeting. Thanks for your attention. Sincerely yours, John H. Schwartz M. D. This message is intended for the sole use of the individual to whom it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the addressee you are hereby notified that you may not use, copy, disclose, or distribute to anyone the message or any information contained in the message. If you have received this message in error, please immediately advise the sender by reply email and delete this message.

TAG

Subject: Physician opinion opposed to SE 138

Date: Tue, 8 Apr 2003 13:39:56 -0800

From: "Janssen, Andrew" <ajanssen@provak.org>

To: "Senator_Fred_Dyson@legis.state.ak.us" <Senator_Fred_Dyson@legis.state.ak.us>

CC: "Janssen, Andrew" <ajanssen@provak.org>

Dear Senator Dyson:

I am writing regarding Senate Bill 138 that would repeal the current statues that allow for collaborative relationships between physicians and pharmacists. As a family practice resident in Anchorage I have many elderly patients who cannot easily afford health care and need as much "team" assistance as possible. Medical research has shown that Coumadin Clinics, as we have at the residency, provide substantially better care to many elderly patients who need coumadin to prevent strokes. This is a great relationship between physicians and pharmacists.

I strongly urge you not to pursue SB 138 as it would compromise the care many physicians provide to their patients.

Thank you for your time and effort.

Respectfully,

Andrew Janssen, MD

This message is intended for the sole use of the individual to whom it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the addressee you are hereby notified that you may not use, copy, disclose, or distribute to anyone the message or any information contained in the message. If you have received this message in error, please immediately advise the sender by reply email and delete this message.

The Honorable Senator Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, AK 99801-1182

March 27, 2003

RE: SB 138, Collaborative Practice Authority Repeal

Dear Senator Dyson,

I must ask you to reconsider your bill SB 138. This bill will undermine the cooperation and collaboration that physicians and pharmacists have practiced for decades. Pharmacists have worked with physicians, nurses, and patients to provide smooth integration of care, to decrease over all healthcare costs, and improve patient outcomes.

The Board of Pharmacy regulations concerning collaborative practice were issued on the request of the profession and other health care professionals *to help formalize and regulate a standard of practice* that has been practiced in hospitals and community setting for years. It does not issue prescriptive authority to pharmacists.

Pharmacists are extensively qualified, due to our length and depth of training, to implement a physician directed protocol. As laid out in the collaborative practice regulations, these interventions are shown to improve patient care. Many studies have shown that by improving patient health through collaborative practice -type protocols, the overall health dollars spent is drastically reduced. In addition these types of interventions help free the already limited time of busy physicians.

To repeal this regulation will not bring the profession of pharmacy back to the time just prior to the enactment of these regulations, but will undo the last 30 years of pharmaceutical advancement in community and hospital practice.

It is in the interest of patient's well being that I implore you to withdraw this bill, SB 138.

Sincerely,



Pharmacist

2685 Mill Bay Rd.
KODIAK, AK 99601
907-486-6040

The Honorable Fred Dyson
Alaska State Senate
State Capitol, Room 121
Juneau, AK 99801-1182

RE: Senate Bill 138 - Collaborative Practice Authority Repeal

Dear Senator Dyson,

I must ask you to reconsider your bill SB 138. This bill you have introduced is a legislative bill which will undermine cooperation and collaboration that physicians and pharmacist have practiced for decades.

We, as pharmacists, have worked with physicians, nurses, patients, and other health care providers to provide

- smooth integration of patient care,
- to decrease cost, and
- improve patient outcomes.
- Increase patient understanding of how drugs are tools in health care and how that proper relationship leads to better outcomes
- The Board of pharmacy regulations was issued on the request of the profession and other health care professionals to
 - help formalize and regulate a standard of practice that have been practiced in hospitals and community settings for years,
 - it does not issue prescriptive authority as other providers have been granted by the state over the past years,
 - though we feel that we are ultimately qualified because of our back ground, length, and depth of training we are asking only to implement agreed on, in advanced, physician orders to better patient care.
 - to recognize formally, collaborative agreements with other health care providers that have already existed for years.
 - to help coordinate care to have more consistant outcomes
 - thus reduce costs and improve patient outcomes
 - by taking care of maintenance and pre-authorized changes,
 - freeing up the limited time of other busy providers.
 - we can take a turn around in order changes normally now of 4 hours to 2 weeks, to if collaborative care is available, as little as 10-20 minutes.
 - saving time, dollars, and improving patient outcomes.

The Republican platform is and has been to have less government interference, to increase efficiencies by letting business do its job better, this bill will run counter to that mandate. It will actually bring chaos to the delivery of health care by slowing down communication. The legislature has many pressing issues this year to resolve, to take time for this issue, violates fundamental party platforms. Allow the legislative body to spend more time on real issues, to efficiently run state government, that is the legislature's mandate. Let the boards that represent the state regulate the profession., that is their mandate. Please withdraw SB 138.

Sincerely Yours,
Gerald KW Brown, president
Alaska Pharmacist Association
PO Box 70196
Fairbanks, Alaska 99707
gkwbrown@alaska.com
907-452-1514(W) 907-452-1917(Fax work)

File PRESCRIPTIVE AUTHORITY

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT IN ANCHORAGE

ALASKA STATE MEDICAL ASSOCIATION, an Alaska Corporation,

Plaintiff,

vs.

THE STATE OF ALASKA, Department of Community and Economic Development, Division of Occupational Licensing, Board of Pharmacy,

Defendants.

Case No. 3AN-02-_____ CI

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff complains against the defendant as follows:

- 1. Plaintiff is an Alaska Corporation in good standing, which has paid all taxes and filed all reports which are due and is in all respects qualified to prosecute this action. Plaintiff's membership consists of licensed physicians, resident physicians and medical students in the State of Alaska currently engaging in the practice of medicine.
2. Defendant Board of Pharmacy ("the Board") is a Board statutorily created pursuant to AS 08.80.010 et. seq.

COMPLAINT FOR PERMANENT INJUNCTION ALASKA STATE MEDICAL ASSN V. SOA CASE NO. 3AN-02-_____ CIVIL

3. The Pharmacy Board has adopted a regulation, 12 AAC 52.240 ("the regulation") which purports to allow pharmacists to enter into a collaborative practice agreement the terms of which allow the pharmacist to initiate or modify drug therapy in accordance with a written protocol, make therapeutic decisions and engage in other medical, dental and/or nursing activities. The regulation also allows the Board to determine whether or not the pharmacist has been adequately trained in the procedures outlined in the protocols.
4. The Board has acted outside the scope of its statutory authority by adopting this regulation and is therefore in violation of AS 44.62.020 and .030.
5. Plaintiff is entitled pursuant to AS 44.62.300 to bring this action for a judicial declaration that the regulation is invalid.
6. The regulation violates AS 08.80.261(9) which prohibits a pharmacist from dispensing a controlled substance without a specific prescription.
7. The regulation violates AS 08.80.295(a) by allowing a pharmacist to prescribe without a specific prescription.
8. The regulation violates AS 08.80.480(21) (27) (30) and (31) by allowing pharmacists to operate beyond the statutorily prescribed boundaries of the practice of pharmacy and engage in the activities which are reserved by statute to practitioners authorized to prescribe and administer drugs in the course of their professional practice.
9. The regulation invades the statutorily granted authority of the Medical Board to prescribe regulations governing the responsibilities of supervising physicians (AS

COMPLAINT FOR PERMANENT INJUNCTION
ALASKA STATE MEDICAL ASSN V. SOA
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08.64.107 (4)) as well as the statutorily granted authority of the Medical, Dental and Nursing Boards to regulate the practice of medicine, dentistry and nursing (AS 08.64.100, 08.36.075 and 08.68.160.)

10. The regulation violates AS 08.64.170, 08.36.100 and 08.68.160 by granting pharmacists the right to engage in practices that are only authorized to be performed by persons licensed under AS 08.64, 08.36 and 08.68.

11. The regulation violates AS 08.64.380(6)(A), 08.36.360 and 08.68.410(8) by allowing pharmacists to practice medicine, dentistry and/or nursing without a license.

12. The regulation violates 12 AAC 40.967(8) which makes it unprofessional conduct for a physician to delegate responsibilities that require a license or permit under AS 08.64 to persons who do not possess the appropriate education, training, or licensure to perform the responsibilities.

13. The regulation allows the Board to determine the training and competence of those who are making decisions concerning the initiation or modification of drug therapy, making therapeutic decisions, monitoring patients and engaging in other medical, dental and/or nursing activities. These determinations are beyond the scope of the Board's authority, beyond the competence of its members and invade the province of the Medical, Dental and Nursing Boards.

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14. The Board has actually approved numerous protocols pursuant to this regulation, all of which violate the statutes and regulations cited above. Each of these protocols poses a potential threat to the health and safety of medical patients in the State of Alaska.

A. Exhibit A is an agreement which allows pharmacists employed by the SEARHC Clinic Juneau Pharmacy to initiate warfarin therapy, gather appropriate subjective data, adjust dosage following guidelines set up for physicians, deviate from those protocols if the pharmacist decides the clinical situation warrants, assess vital signs and interpret medical histories.

B. Exhibit B is an agreement which allows pharmacists employed by the Providence Alaska Medical Center pharmacy to manage anticoagulant therapy including patient assessment of signs and symptoms of acute medical problems and/or complications including bleeding, drug intolerance, and thrombotic events; change dosages; prescribe by phone; and document their assessments in the patient's medical chart.

C. Exhibit C is an agreement which allows pharmacists employed by the Providence Alaska Medical Center pharmacy to dose or adjust doses of numerous medications; assess patients' response to these doses; therapeutically exchange medications; monitor patients' blood levels; determine if dosages are safe and therapeutically optimal; assess renal function, EKG, electrolytes and other lab tests; determine what lab tests are appropriate; write doses for specific

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medications not specified in usual protocols; write orders in the patient's medical charts; assess the patient's status and therapeutic progress; develop action plans; and manage patient therapy solely by the pharmacist at the request of a physician.

D. Exhibit D is an agreement which allows pharmacists employed by the Fred Meyer Pharmacy in Anchorage to dispense emergency contraceptive pills after assessing the need for the pills; make judgments concerning whether or not the patient could be pregnant or have contacted a sexually transmitted disease; and counsel the patient on medical options.

WHEREFORE, plaintiff requests the following relief from the Court:

1. Declare 12 AAC 52.240 null and void and order it struck from the Alaska Administrative Code.
2. Permanently enjoin the Division of Occupational Licensing and/or the Pharmacy Board from enforcing the regulation and/or adopting any further protocols pursuant to that regulation.
3. Declare any protocol established and approved by the Division of Occupational Licensing and/or the Pharmacy Board pursuant to 12 AAC 52.240 be null and void.
4. Order the Division of Occupational Licensing and/or the Pharmacy Board to notify any person or entity which is a party to any protocol established and approved pursuant to 12 AAC 52.240 that the protocol is null and void.
5. Award the plaintiff its costs and attorney's fees.

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6. Grant the plaintiff such other and further relief as may be appropriate.

DATED at Anchorage, Alaska this ____ day of December, 2002.

BISS & HOLMES
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By: _____
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