ALASKA STATE LEGISLATURE
JOINT COMMITTEE ON
ADMINISTRATIVE REGULATION REVIEW
January 30, 2001
9:37 a.m.

HOUSE MEMBERS PRESENT

Representative Lesil McGuire, Chair
Representative Jeannette James
Representative Joe Hayes

HOUSE MEMBERS ABSENT

All House members present

SENATE MEMBERS PRESENT

Senator Georgianna Lincoln

SENATE MEMBERS ABSENT

Senator Robin Taylor, Vice Chair
Senator Lyda Green

OTHER LEGISLATORS PRESENT

Representative Gretchen Guess

COMMITTEE CALENDAR

Overview of Committee by Chair, Rep. Lesil McGuire
Tam Cook Legislative Legal, Review of Cmte Powers
Deborah Behr Dept of Law, Law's Review of Regulations
Board of Pharmacy Review

PREVIOUS ACTION

No previous action to record

WITNESS REGISTER

TAMARA COOK, Director
Legal and Research Services
Legislative Affairs Agency
Alaska State Legislature

Capitol Building
Juneau, Alaska 99801
POSITION STATEMENT: Reviewed the powers of the committee.

DEBORAH BEHR, Assistant Attorney General
Legislation & Regulations Section
Civil Division(Juneau)
Department of Law
PO Box 110300
Juneau, Alaska 99811-0300
POSITION STATEMENT: Presented the Department of Law's review of regulations.

CATHERINE REARDON, Director
Division of Occupational Licensing
Department of Community & Economic Development
PO Box 110806
Juneau, Alaska 99811-0806
POSITION STATEMENT: Reviewed the Board of Pharmacy regulations.

DR. COLLEEN MURPHY
(No address provided.)
POSITION STATEMENT: Expressed her interest in [collaborative agreements with pharmacists] proceeding.

LIS MERTEN
National Association of Chain Drug Stores
(No address provided.)
POSITION STATEMENT: Testified in support of the Board of Pharmacy regulations.

ROD SHAFER, Executive Director
Washington State Pharmacist Association
1501 Taylor Avenue SW
Renton, Washington
POSITION STATEMENT: Reviewed Washington's experience with collaborative agreements involving pharmacists.

MARK BOHRER, Pharmacist
Member, Board of Pharmacy
19725 Highland Ridge Drive
Eagle River, Alaska 99577
POSITION STATEMENT: Offered additional information.

SHIRLEY CORSEY, Consultant Pharmacist
in Geriatrics
Providence Hospital

25740 Berryhill Road
Eagle River, Alaska 99577
POSITION STATEMENT: Offered additional information.

GARY GIVENS, President
Alaska Pharmaceutical Association
Pharmacy Director, Alaska Native Medical Center
19638 Delphin Circle
Eagle River, Alaska 99577
POSITION STATEMENT: Offered additional information.

BARRY CHRISTENSEN, Pharmacist
3526 Tongass Avenue
Ketchikan, Alaska 99901
POSITION STATEMENT: Discussed collaborative agreements.

ACTION NARRATIVE

TAPE 01-1, SIDE A
Number 001

CHAIR LESIL McGUIRE called the Joint Committee on Administrative Regulation Review to order at 9:37 a.m. Representatives McGuire, James, and Hayes were present at the call to order. Senator Lincoln arrived as the meeting was in progress. Representative Guess was also in attendance. Chair McGuire invited Ms. Cook to begin her review.

REVIEW OF COMMITTEE POWERS

Number 0057

TAMARA COOK, Director, Legal and Research Services, Legislative Affairs Agency, Alaska State Legislature, began by saying that the Joint Committee on Administrative Regulation Review (ARR) is a permanent interim committee of the legislature that has been established in statute. The general powers of ARR is set out in AS 24.20.460. She explained that the committee was formed to review the adoption of regulations by the executive branch and consider them in terms of whether or not those regulations accomplish legislative intent. Ms. Cook noted that paragraph (4) AS 24.20.460 provides the committee the authority to consider proposed regulations. The committee is not limited to review of regulations that are adopted and filed. The committee can get involved earlier in [the regulation-making/adoption] process.

Number 0187

MS. COOK emphasized the importance of the Supreme Court's ruling in 1980, which restricted the power of ARR with respect to some of the statutory provisions. Those statutes have never been amended or repealed subsequent to that ruling. Ms. Cook explained:

> Essentially, the Administrative Regulation Review Committee, by statute, has the authority to recommend to the full legislature that they consider the annulment of a regulation by resolution. ...the mechanism whereby the legislature can exercise the legislative veto of a regulation was held unconstitutional in the case State v. A.L.I.V.E. Voluntary. So, it doesn't do either the committee or the legislature any good to submit such a recommendation now, to the full legislature. In addition, the same case, I think, makes it fairly clear that the power of suspension that appears in the statutes for the [Administrative] Regulation Review Committee at [AS] 24.20.445 is not going to be upheld by a court, if you attempted to exercise it. Now, that provision essentially ... purports to give the committee the power to suspend the effectiveness of a regulation that it has objections to. And it seems to me, quite clear, that the committee cannot act to that level. Essentially, the court, in State v. A.L.I.V.E. held that if the legislature wishes to take an action that has binding legal effect ... on others, a third party's, that it must act by using the enactment procedures that are set out in the state constitution. That is, it must pass a law. There must be three readings, there must be a required vote separately by each house. The subject must be reflected in the bill and above all, a piece of legislation is, of course, subject to veto by the governor, subject to being overridden by the legislature. So, it is those provisions that our court held define the scope of the power of the legislature to effect the rights of third parties (indisc.). So, I think it is important to bear in mind that while the committee cannot make a recommendation that the legislature effectively use its legislative veto authority through the use of a resolution, there is nothing that prevents the legislature from doing what it has always done and that is enacting laws.

MS. COOK continued:

> A regulation is essentially a legislative power that is exercised by the executive branch of government pursuant to a delegation by the legislature itself. The legislature can always withdraw a delegation ... to a certain extent. So, one of the things that ... the committee can certainly do in response to concerns about a regulation is to look at the underlying legislation and consider modifying the legislation in a way that meets the concerns of the committee. The committee has the right to introduce legislation through the Rules committee. So, that ... course of action is always available to the legislature and to the committee to pursue and remains, probably, its most potent tool. That and, I would say, participation in the regulation process at the proposal stage is potent.

Number 0454

MS. COOK said:

> The other thing that I would like to draw the attention of some of the members of this committee to is the fact that not every regulation, a fair number of them now, ... is adopted under the Administrative Procedure Act [APA]. There are a great many regulations in areas, where the legislature has itself made the policy determination that they were going to give a particular agency or, in the case of the railroad, a public corporation the ability to adopt regulations without complying with the APA. Now, obviously, they comply with some sorts of due process requirements attached, but they're not necessarily Administrative Procedure Act regulations. And, I think a lot of people do not understand this. There's nothing that prevents this committee from getting involved in those sorts of regulations as well, even though they're not subject to the same kind of process that you see. Now, ... the APA actually has a provision that says that proposed regulations are going to be delivered to the committee for its review. Some of the other provisions where you see a statute that says an agency may adopt regulations it does not have to follow the APA, it also goes on to say that

> those regulations shall be submitted to the committee for its review. In many cases, there's such ... an independent statement, but not in all. Nevertheless, I think it's quite clear that this committee could consider regulations from sources where the adopting agency is not required to comply with the APA. And so, that was a point that I thought I ought to make.

MS. COOK offered to answer questions from the committee.

Number 0584

CHAIR McGUIRE related her belief that there is actually a lot of misconception about what ARR can and cannot do. She noted that the committee packet includes Ms. Cook's overview of the committee's power.

REPRESENTATIVE JAMES commented that ARR has, in the past, been successful in negotiating [changes] with the agency during the writing of the regulations. She emphasized that this committee can make a difference without introducing legislation.

Department of Law's Review of Regulations

Number 0713

DEBORAH BEHR, Assistant Attorney General, Legislation & Regulations Section, Civil Division(Juneau), Department of Law (DOL), informed the committee that she is the person who signs-off on all the aforementioned APA regulations. Ms. Behr noted that Steve Weaver, also in the Legislation & Regulations Section, is available to answer regulatory questions on particular projects. She noted that the committee packet should include the current "Administrative Drafting Manual for Regulations." "All state agencies that are required to comply with the APA must meet this," she said. This manual, which can also be found on the Department of Law's home page, highlights all the different steps in the regulatory process. She offered to give the committee or its staff a separate briefing on the manual. The committee packet should also contain a document labeled, "Exhibit 1," which is the Alaska Administrative Code (AAC) contacts for the executive branch. She explained that the governor adopted an Administrative Order, which requires that each department have an administrative [regulatory] contact. She identified this contact person as "one stop shopping" for that particular department and although this person may not know all the details, he/she will know how to obtain them.

Number 0878

MS. BEHR turned to two recent statutory provisions. She first addressed the statutory provision requiring that administrative regulations be posted on the online public notices [site]. She directed the committee to the document entitled, "Exhibit 2." The online public notice system is running and all the state agencies are using it. She pointed out that the site has a copy of the notice for the regulations, which specifies when and where the hearings are. Furthermore, if regulations have been adopted, it provides a summary of those regulations. Ms. Behr then addressed the statutory provision regarding e-mail to legislators and the need for legislators to receive e-mail as fast as possible. She related her understanding that this is being implemented by all agencies that have to do APA regulations. She said that she has heard that has been quite successful.

Number 0966

MS. BEHR announced that she would now focus on a pared down presentation regarding how DOL reviews regulations. She again offered to provide the committee or its staff with a separate briefing on this matter. Ms. Behr directed the committee's attention to a document entitled, "Exhibit 3," which is a checklist that DOL uses to review regulations. She emphasized that DOL's statutory duties to review APA regulations is a legal review not a policy review. This review is a two-level review in which an agency attorney is assigned to every project and thus each project will include someone who deals with the particular area of law on a daily basis. Then the review moves up to Ms. Behr's level where [the project] is reviewed on the basis of whether it complies with the statutes and the constitution. She noted that APA establishes the requirements for the timeframes regarding how long regulations should be available for public comment and when the regulations can be adopted, the types of hearings required, and the types of documents required. Ms. Behr said that she reviews all that information and the procedure followed.

MS. BEHR remarked that the committee is probably most interested in her legal review of the substance [of the regulations]. She explained that first she reviews whether the state agency has regulation-writing authority. Next, she would review whether the regulation is consistent with the statutes. She noted that she would also review whether the regulation

meets the legal requirement to be reasonably necessary to carry out the statute for which she generally defers to boards, commissions, and commissioners. She pointed out that she would question [a regulation] if it looked like it is outside the range of what a court would approve. Finally, Ms. Behr reviews whether the regulations meet the state and federal constitutions, which she remarked to often be the most difficult part of the review.

Number 1229

MS. BEHR turned to the issue of how long it takes to do a project, to which she said it depends. However, once a regulation is approved for filing by the lieutenant governor, it goes to the lieutenant governor who now has limited review authority. The legislature gave the lieutenant governor the ability to review "nonboard" regulations on the basis of failing to faithfully execute the laws and give the agency more time to respond to specific issues raised by ARR. The committee has the opportunity to submit comments during the public comment period and the lieutenant governor can review whether those comments were responded to appropriately. Ms. Behr echoed Ms. Cook's comment about the committee commenting during the public comment period. She offered to answer any questions.

Board of Pharmacy Review

CHAIR McGUIRE announced that the committee would now hear the review of the Board of Pharmacy.

Number 1363

CATHERINE REARDON, Director, Division of Occupational Licensing, Department of Community & Economic Development, informed the committee that her division oversees the Board of Pharmacy, which adopted regulations on January 12, 2001. These regulations authorize collaborative agreements between pharmacists and physicians or other prescribing health care professionals. She pointed out that these regulations have not yet been approved by DOL and that process may take several months. If these regulations were approved by DOL, Ms. Reardon projected the results of these regulations would be evident in the summer. She noted that the regulations should be in the committee packet.

MS. REARDON referred to page 2 of the regulations, which inserts a new section entitled, "Pharmacist Collaborative Practice

Authority." She noted that she would refer to physicians for purposes of discussion, although this collaborative agreement could be with any practitioner authorized to prescribe drugs under AS 08. She reviewed what the regulations required in the protocol as specified in the new section 12 AAC 52.240 (b) (1)-(7). She pointed out that this [collaborative agreement] would be restricted to legend drugs, nonnarcotics. Furthermore, this written agreement must be submitted to the Board of Pharmacy, who must approve it before the relationship is established.

Number 1573

MS. REARDON referred to the final section of regulations entitled "Monitoring of Drug Therapy By Pharmacists." This section would allow a physician to establish an agreement with a pharmacist. For example, the monitoring may be such that when an asthma patient comes in each month for refills, the pharmacist tests this patient to determine the amount of air the patient can breath and depending upon the results the pharmacist can either renew the prescription or call the physician.

MS. REARDON emphasized that [these regulations] deal with the Board of Pharmacy. [These regulations] would allow pharmacists to enter into these [collaborative] agreements under the specific conditions. However, the Medical, Nursing, and Dental boards would retain their ability to govern how their professionals behave. Therefore, those boards could choose to write their own regulations. Furthermore, the Medical Board retains the ability to establish the rules for doctors and thus can make these rules more restrictive than the pharmacy regulations, if the Medical Board wanted to engage in a regulation project. The case would be the same for the Nursing and Dental boards as well. Ms. Reardon explained that she mentioned this due to the concern surrounding the broadness of the regulations. The broadness of the regulations may be advantageous to the other boards because each profession can tailor [its regulations] or perhaps choose not to engage in [collaborative agreements]. Ms. Reardon also emphasized that these agreements are voluntary and optional. Furthermore, these collaborative agreements could be focused such that it refers to a specific patient or board such that it refers to a class of people. She noted that the Board of Pharmacy did discuss these regulations at five different meetings; this has been a two year process.

Number 1789

MS. REARDON informed the committee that an Anchorage physician had asked whether the agreement she is contemplating with local pharmacists to provide emergency contraception would conform to Medical Board standards. On January 19 the Medical Board wrote that this physician could enter into an agreement for the emergency contraceptive care after the pharmacy regulations take effect, as long as the physician ensures the pharmacist has appropriate education and training. She emphasized that this collaborative agreement is not specifically directed at emergency contraceptives.

MS. REARDON concluded by reminding the committee to keep in mind the current realities of health care. She related her impression that some of these collaborative relationships between pharmacists and physicians may be occurring now. For example, in a hospital physicians may be delegating certain responsibilities to pharmacists. She also posed the possibility that physicians may [already] be requesting that pharmacists refill all their patients' prescriptions once during the physician's absence. Therefore, perhaps these regulations would provide some form and documentation of the collaborative relationships [that already exist].

MS. REARDON addressed the issue of fragmentation of care. She posed an example in which an individual obtains a flu shot from a pharmacist who has an agreement to administer the flu shot, but the agreement is not with that individual's physician. In such a case, there is concern regarding how that individual's physician would know that he/she had that treatment.

Number 1978

DR. COLLEEN MURPHY testified via teleconference. She emphasized the importance of passing these regulations in order to cover the current practice of medicine and pharmacy. She pointed out that the majority of Anchorage hospitals currently have pharmacists working in collaborative relationships with physicians. Furthermore, pharmacists and physicians are working collaboratively as Ms. Reardon stated earlier. Dr. Murphy informed the committee of a physician who had signed a collaborative agreement with a local pharmacy in order to provide the flu vaccine and the nuemococol(ph) vaccine under his prescriptive authority.

DR. MURPHY turned to the issue of fragmentation of health care and stated, "it's not really fragmentation, it depends on how you choose to work with your health professional colleagues."

She said that she would like to think that [health professionals would work] collaboratively. Dr. Murphy expressed the need for any collaborative practice agreement to have the option for the patient to request for the encounter provided through the pharmacist to be faxed to the primary care physician. Therefore, the fragmentation could be easily overcome. Dr. Murphy mentioned that other states with collaborative agreements have demonstrated that some patients don't want their primary care physician to know about the care sought outside their office. In conclusion, Dr. Murphy expressed her interest in [collaborative agreements with pharmacists] proceeding.

REPRESENTATIVE JAMES related her understanding that in many cases, the pharmacist may be more familiar with certain medications than a physician. She asked what emergency contraception is.

CHAIR McGUIRE, upon determining that Dr. Murphy was not online, announced that Representative James' question would be held until Dr. Murphy was back online.

Number 2156

LIS MERTEN, National Association of Chain Drug Stores, testified via teleconference. Although she said that she was mainly interested in listening to the hearing, she noted support of the regulations being discussed. Ms. Merten echoed Ms. Reardon's earlier statement that these [collaborative] arrangements are voluntary.

SENATOR LINCOLN noted that Washington has had collaborative agreements for some time and thus she asked if there have been any problems. She also asked if Alaska's regulations are similar to Washington's regulations.

MS. MERTEN deferred to Rod Shafer.

Number 2232

ROD SHAFER, Executive Director, Washington State Pharmacist Association, noted that he has provided the committee with a packet of information of which one side includes information provided at the National Conference of State Legislators. That information includes studies that document the value pharmacists bring to the health care arena, that is value in patient outcomes and dollars saved. The second portion of the information addresses pharmacists' contributions in

collaborative practice arrangements. He said that information reviews what collaborative practice arrangements are and the advantages of such. He noted that the committee should also have information regarding medication use in the U.S. There is also a section that addresses the potential dollars that pharmacists' services in collaborative arrangements could save Medicaid.

MR. SHAFER then turned to the Power Point presentation that reviews what has happened in Washington. In 1979 Washington enacted the [collaborative practice agreement] laws and in 1980 the rules were promulgated and subsequently approved in 1981. Therefore, Washington has about 20 years of experience with [collaborative agreements]. He referred the committee to a document entitled, "1993-1999 Survey Goals" that measured the satisfaction from the pharmacist and the prescriber, the frequency of use of these arrangements, and defined the impact, and determined whether the Board of Pharmacy should promote these arrangements as an effective way of promoting health care. In 1999 "we" reviewed what quality insurance measures were included in these collaborative practice agreements as well as what type of data was collected. He informed the committee of the following information [that was obtained from the surveys]. In 1993 there were 57 protocols on file with the State of Washington, the majority of which were with hospitals and HMOs (health maintenance organizations). Of those 57 protocols, 44 responded. He indicated that 135 prescribers and 84 pharmacists responded as well. Mr. Shafer directed attention to the following information: "utilization with seven pharmacists and 27 physicians per protocol." He remarked that many of these protocols had to do with group practices, which results in the skewed numbers. In 1999 the number of protocols has grown to 358, which doesn't include the 153 protocols for the provisions of emergency contraception ...

TAPE 01-1, SIDE B

MR. SHAFER indicated that 88 of those participating responded, of which "double the amount of pharmacists and physicians ... sent in their surveys." He specified that the type of prescriptive authority being looked at is the initiation of therapy, the modification of [therapy], and the continuation [of therapy]. He explained that the initiation could be as simple as someone requesting a flu shot, which the pharmacist gives. Or, the initiation could be such that a physician writes an order and sends a patient to the pharmacy-based pain clinic. The order could instruct the pharmacist to control the patient's

pain per protocol. Modification of therapy would be in the case of a patient who is already on some protocol and the pharmacist reviews the protocol [in case] there are extenuating circumstances that prevent compliance with the treatment protocol. Mr. Shafer reminded the committee that today there are over 10,000 drugs available. Furthermore, the treatment modalities are very complex and someone needs "to hold their hand through that process and we think the pharmacy plays a huge role in that." He indicated the need for the physician and pharmacist to work together in order to have the results desired by the physician, pharmacist, and patient. The continuation [of therapy] is similar to the aforementioned example of [a physician] being gone and requesting that [a pharmacist] refill the patient's prescription [based on the agreement].

MR. SHAFER emphasized that in Washington today 35 percent of all protocols are in chain pharmacies, 26 percent of the protocols are independent and 20 percent of the protocols are in medical. Therefore, about 78 percent of these protocols are occurring in ambulatory care settings not in institutional settings. This illustrates that more care is moved into the community where people are. Mr. Shafer identified "the next great 'Aha' in health care" as occuring when there is the realization that when health care is where people are, they will access it. He continued, "When we make it difficult for them to access health care, then they don't and we end up with people who are very sick when they finally get to our doorstep." This is exemplified with immunizations such as that for the flu shot. Pharmacists in the State of Washington provided over 135,000 flu shots last year.

Number 2272

CHAIR McGUIRE asked if there have been any lawsuits that resulted from [collaborative agreements]. She noted discussions that she has had regarding whether physicians in Alaska can delegate any of their healing authority. She inquired as to the liability for the physician, if those authorities are delegated at the various stages.

MR. SHAFER answered, "After 20 years we've had no complaints, no lawsuits, no incidence of a patient who has been harmed. Not one."

MR. SHAFER continued with the results of these protocols after 20 years. In 1993 there was a 98 percent satisfaction rate from physicians involved with these. He did note that there was one

physician and one pharmacist who were unhappy with their protocol, however, it didn't result in anything bad happening to patients. In 1999 there was a 95 percent satisfaction rate [from physicians involved with these protocols] and pharmacists were also satisfied. He turned to the quality assurance measures and noted that in 50 percent of the cases, there was case review by the pharmacist and the physician. He noted other quality assurance measures, such as chart audits, [the collection of data in regard to] adverse drug reactions, and complaints. He said that there is no review 34 percent of the time. Mr. Shafer informed the committee that the Washington Medical Association has a policy that says it is not opposed to collaborative practice agreements between physicians and pharmacists and other health care providers as long as it is on a one-to-one basis. In most cases, [the Washington State Pharmacists Association] agrees with that. He could think of two cases, emergency contraception and immunizations, that would need a broader base protocol. In fact, the Washington Medical Association has a resolution that endorses the provision of emergency contraception and immunization by pharmacists.

Number 2097

MR. SHAFER turned to the outcome data collected. In regard to whether the set goals were being achieved, 48 percent of the time [the goals were met]. He noted that 44 percent of the time patient satisfaction and quality of life issues were reviewed. Eighteen percent of the time access to care was being reviewed. He indicated that these collaborative agreements do improve access to care because the most accessible health care professional is the pharmacist. The equivalent of the U.S. population walks through a pharmacy once a month, which provides huge opportunities for education and "hand holding." He noted the collection of data regarding adverse events.

MR. SHAFER moved on to the perceived impacts from the prescribers on the patient. He commented on the physicians' [perception that these collaborative agreements] increased patient convenience, decreased costs, and increased the quality of care. The pharmacists' perception was a bit higher. With regard to the [Washington] Board of Pharmacy's recommendation regarding whether pharmacists should promote collaborative drug therapy management as a method of improving patient outcomes, 76 percent of prescribers responded in the affirmative. Of course, pharmacists had a higher approval rating. No one expressed the need to discourage this type of collaboration. Mr. Shafer reminded the committee that health care is based on protocols.

Number 1976

MR. SHAFER informed the committee that "we" didn't survey the 153 emergency contraception protocols that are in place. He explained that RU486 is not available to pharmacists nor do pharmacists want to have the ability to handle that drug in the situations it would be used. However, the emergency contraception provision - the morning after pill - is merely a doubling of the dose of a standard birth control pill that must be taken within 72 hours of unprotected intercourse. Most importantly, if the egg is fertilized and implanted, the woman is pregnant and the emergency contraception product can do nothing. He stated, "If you are pregnant, you are pregnant." However, if the egg is not implanted, the emergency contraception product may slow the [implantation] process. Currently, there are two products available, one of which is referred to as Plan B. Mr. Shafer emphasized that "this" is nothing new as it has been known for 20 years and has been available in physician's offices. Planned Parenthood has been providing this [emergency contraception] for a number of years in every state. In the State of Washington "they" provide about 5,000 interventions for women in a year. The first year that pharmacists began to provide this [which includes an assessment and counseling] to women that came in, the pharmacist did 12,000. He attributed that increase to making [emergency contraception] more accessible to people. He noted that this is on track in the second year with additional federal funding to expand into rural Washington, which he estimated would increase the interventions to about 24,000. Mr. Shafer informed the committee that the State of Washington spends about $100 million, during conception to birth, on unintended pregnancies.

Number 1855

SENATOR LINCOLN referred to the correspondence from the Alaska State Medical Board and the Alaska Board of Dental Examiners, one of which is reluctant to proceed with the collaborative agreement and the other is opposed to it. She asked if, 20 years ago, the State of Washington faced those same concerns. If so, she asked how Washington was able to overcome the fears.

MR. SHAFER pointed out that 30 states currently have collaborative drug therapy management. The remaining states are in the same situation as Alaska. He remarked that [collaboration] is generally accepted as good medical practice. The difference between Washington in 1979 and Alaska now is that

in 1979 everyone was making money. However, today the issue seems to be about "turf" and whether such arrangements would take money and patients away from certain groups. He said there seems to be two levels of rhetoric. Mr. Shafer also pointed out that the American Medical Association has passed an ordinance that "the provision of emergency contraception should be over-the-counter. How you leap over having the pharmacist provide and give an assessment to actually just anybody can walk in off the shelf, is an interesting jump for me."

SENATOR LINCOLN returned to the topic of the morning after pill. She related her understanding that if the egg is fertilized, the morning after pill won't help. Furthermore, the literature in the packet says that if the egg is fertilized and the morning after pill is taken, it won't damage the fetus or harm the mother. She indicated the need for Mr. Shafer to expand on that.

MR. SHAFER explained that an egg can be fertilized and not implanted. In such a case, the morning after pill will prevent implantation. However, if the egg is fertilized and implanted - the woman is clinically pregnant - it does nothing to abort that nor does it do any harm to the fetus.

Number 1658

REPRESENTATIVE JAMES related her experience with her own pregnancy in which her [egg] was not attached well enough. Therefore, she questioned what would happen [if the woman took the morning after pill] in a situation such as hers.

MR. SHAFER answered, "If the fertilized egg is implanted in any manner, there is no way that this morning after pill is going to dislodge that and that becomes a ... medical issue that needs to be dealt with by your physician."

REPRESENTATIVE JAMES remarked that if these contraceptives are currently only given by prescription and this can be given without prescription, it would seem that it should be over-the-counter. If this is serious and needs a prescription, then it would seem that not having a prescription is problematic. In response to Chair McGuire, Representative James said that Mr. Shafer had answered her question [and thus hearing from Dr. Murphy wasn't necessary]. Representative James remarked that "emergency contraception" seems to be a misnomer.

MR. SHAFER noted that his card was included in the committee packet if the members need further information.

ERIN CAREY BYRNE, Alaska Pharmaceutical Association, announced that she would cede her time to a panel of folks that have come down from Anchorage. She introduced the panel members: Shirley Corsey, Gary Givens, and Mark Bohrer. All three of these pharmacists are involved in some form of a collaborative care arrangement.

MARK BOHRER, Pharmacist; Member, Board of Pharmacy, addressed the [aforementioned suggestion] of the danger of emergency contraception being over-the-counter. Mr. Bohrer said, "I think having a health care professional involved is the potential to counsel them or refer them to a physician for future contraceptive needs so they don't have to rely on this method as a form of contraception; to get it back in the loop of providers."

REPRESENTATIVE JAMES asked, "The morning after pill -- does that mean that this person ... does not have a prescription for birth control pills or is this in addition to the birth control pills that they maybe are taking .... What is the connection between doing that and taking a regular dosage?"

SHIRLEY CORSEY, Consultant Pharmacist in Geriatrics, Providence Hospital, answered that the protocol is the connection. She explained that within the collaborative agreement, the physician has written specific guidelines for a patient that fits [a certain] criteria. This would be similar to a person meeting the criteria to receive a flu vaccination.

REPRESENTATIVE JAMES asked if [the protocol] would be per individual or in general.

MS. CORSEY explained that [the protocol] would be specific to the physician and how the physician writes the criteria for the collaborative agreement.

REPRESENTATIVE JAMES asked, then, if the patient has to be a patient of that [physician].

MS. CORSEY replied no. She explained that the physician would write a protocol that would delegate his authority for persons meeting the criteria [specified in the protocol].

(UNIDENTIFIED SPEAKER) interjected that [the protocol] could be restricted to the physician's patients.

REPRESENTATIVE JAMES expressed concern with a doctor delegating his authority to do something for someone who has never been his patient.

Number 1376

GARY GIVENS, President, Alaska Pharmaceutical Association; Pharmacy Director, Alaska Native Medical Center, said that he thinks this refers to the issue of the independent prescribing authority. He explained that physicians have independent prescribing authority that they can give to someone else, who would have dependent prescribing authority.

REPRESENTATIVE JAMES asked how these patients are given this care or counseling; is there a separate office?

MR. BOHRER informed the committee that he works in the Wasilla Fred Meyer that has a closed room that is used for consultation. He emphasized that he does not discuss health matters when someone is standing in line, especially with something as delicate as [emergency contraception]. In further response to Representative James, Mr. Bohrer said that the drug product is the cost. Currently, emergency contraception is not [provided at the pharmacy level] in Alaska. With the vaccines, there is a $10 charge.

REPRESENTATIVE JAMES clarified that she is interested in how pharmacists are paid for everything -- for treating diabetics, reading lab tests, et cetera.

MS. CORSEY explained that if the [treatment] is directed by a physician as part of a collaborative agreement, then a Health Care Financing Administration (HCFA) form can be completed for Medicaid reimbursement.

REPRESENTATIVE JAMES asked if there is a schedule of charges.

MS. CORSEY answered that Medicaid would determine that.

MR. GIVENS said that it would depend on Medicaid or private insurance for which there are different reimbursements set for each. He recalled that 40 of the states have passed regulations for insurance to reimburse for collaborative care.

Number 1207

MS. SHIRLEY expressed the need for Dr. Murphy or Mr. Shafer to speak to what the prevention of an unintended pregnancy would do to the abortion rate.

DR. MURPHY mentioned that she is a member of the American Society of Emergency Contraception and that she attended the society's national meeting last October. She said that the mechanism of action is being researched as "we" are always looking for more effective ways of "contracepting" women to prevent unintended pregnancy. She informed the committee that "currently the only scientific data around the mechanism of action for emergency contraception appears to be related to delaying the release of the egg." She specified that there is no data to support the theories that [emergency contraception] would interfere with fertilization, the transfer of the egg and sperm, or change the lining of the uterus to interfere with implantation. She expressed the importance of realizing that a huge amount of fertilized eggs never successfully implant. Dr. Murphy discussed results of the experience with birth control pills in early pregnancy.

Number 1055

CHAIR McGUIRE returned to the consultation process. She related her understanding that when prescribing contraceptive pills, the woman must undergo an examination from which she is screened for various tendencies. Therefore, she inquired as to what the procedure would be [from the pharmacist]. She asked, "Is the woman going through a full examination that screens her for any of those potential problems? ...if you aren't, why is it important to do it when prescribing regular oral contraceptives that you take on a regular basis but not the 72-hour pill?"

DR. MURPHY pointed out that unintended pregnancy, cervical cancer, and sexually transmitted diseases (STDs) are three different issues and thus getting pregnant doesn't necessarily cause cervical cancer or [STDs]. Therefore, part of the problem of linking contraception with some of these evaluations is that many women are deterred from coming to a doctor's office because they can't afford the complete evaluation. She noted that some providers are providing "hormone with optional pelvic exam," which means that a history is taken to determine that the patient doesn't have cardiovascular disease, hypertension, or a history of hyper coagulation themselves or in their family and then the birth control is prescribed. The pelvic exam would be

done at a later date. Dr. Murphy informed the committee that basically, the doses of medicine in the current forms of emergency contraception are equivalent to three days of birth control pills. Furthermore, [the 72-hour pill] does not have the same contraindications that a more complex decision for a long-term prescription for birth control pills. She noted that [the 72-hour pill] does not cause blood clots. She said, "Ironically, it's the women that would have high risk pregnancies that emergency contraception might actually best serve."

CHAIR McGUIRE said that she is aware of the distinctions that Dr. Murphy outlined. However, she pointed out, "There is a public policy decision that we're making that removes patients from regular screening with their physicians and that is a concern to recognize. Oftentimes, that might be the only reason that a woman goes in to see her regular physician for the year to get her oral contraceptions or things like that and it might be that one screening that turns up cervical cancer."

Number 0877

MS. CORSEY clarified that the criteria is only for the morning after [pill] not for the long-term use of oral contraceptives. Furthermore, the screening is part of the criteria for the collaborative practice agreement and thus the pharmacist is going over the series of screening questions related to hypertension, et cetera. The woman must meet that criteria. With regard to the long-term relationship with a physician, the State of Washington found that often the woman in need of the morning after pill, which must be taken within 72 hours, needs it after regular business hours or during the weekend. Therefore, access has been such an issue for [the morning after pill]. Furthermore, sometimes people are uncomfortable making an appointment with their physician for this. Ms. Corsey requested that Dr. Murphy or Mr. Shafer speak to the fact that the availability of the morning after pill causes the abortion rate to decrease.

CHAIR McGUIRE commented that she thinks [the committee] has gotten that message. Chair McGuire announced that she didn't mean to make emergency contraception the focus because she felt that the important issue is the relationship between pharmacists and physicians with respect to a variety of drugs. Chair McGuire noticed that the regulations include a procedure for the physician to provide records to the pharmacist. Therefore, she asked if there is a procedure in place by which the records

would be forwarded to the primary caregiver [from the pharmacist].

MS. CORSEY replied yes and emphasized that the feedback loop is important.

Number 0729

REPRESENTATIVE JAMES announced that she supports contraceptives. However, her aforementioned concerns regarding contraceptives [would also be relevant] to all the treatments. Therefore, she expressed the need for those questions to be sufficiently addressed in regulation in order for her to know "that those issues of the treatment of a patient with a doctor will be maintained."

MR. BOHRER referred the committee to 12 AAC 52.240(b)(7), which reads: "a plan for providing the prescribing practitioner(s) with all patient records created under the collaborative practice agreement."

CHAIR McGUIRE indicated the need to take testimony from others present. She announced that she didn't plan for this to be the end of the discussion. She also expressed the hope that the committee's concerns would be taken into account.

Number 0599

CINDY AUDET, Member, Alaska Pharmaceutical Association Board, informed the committee that she also works as a hospital pharmacist in Juneau. She noted her support of inserting language to the professional regulations such that physicians and pharmacists are allowed to have collaborative agreements.

REPRESENTATIVE HAYES related his understanding that these collaborative agreements are being done now without specific [authorizing] language in the regulations.

MR. AUDET informed the committee that she has mainly worked in hospital settings for the past 20 years. In hospital practice, there has been some form of collaborative practice with physicians for as long as she has been involved, although the nature has changed a bit. She explained that what can be delegated [to pharmacists] has evolved from a medical staff decision to the decision of individual practitioners.

REPRESENTATIVE HAYES noted the committee's suggestion that the proposed regulations are too broad. He asked if Ms. Audet felt that the current practice [with collaborative agreements] is broad in scope or narrow.

MS. AUDET replied that it is used in a narrow scope and is based on individual comfort levels and needs.

Number 0441

REPRESENTATIVE HAYES related his understanding from Ms. Reardon that although the [pharmacists] may want a broad scope [with collaborative agreements], the other groups can make their scope as broad or narrow as they like. He asked if that would address some of the committee's concerns.

MS. REARDON answered that she believes those other licensing boards could decide to initiate regulations that would address their concerns, which may in turn address some of the committee's concerns. Ms. Reardon emphasized that although the regulations allow a wide range of [things to be covered with] collaborative agreements, the individual physician still determines what he/she will specifically authorize the pharmacist to do.

REPRESENTATIVE HAYES also related his understanding that the regulations place the onus on the physician to ensure that the pharmacist, with whom the physician is going to have an agreement, has a certain level of education or training.

MS. REARDON clarified that is the view of the [Alaska State] Medical Board. She interpreted the medical board's statement to warn physicians that they will have to report to the board if they are not careful in their relationships.

Number 0258

REPRESENTATIVE JAMES asked if the Dental Board and the [Alaska State] Medical Board would have to pass similar regulations in order to make this [collaborative agreement with pharmacists] work.

MS. REARDON related her belief that if the [Alaska State] Medical Board and the Dental Board are quiet, then these agreements could go forward. If these other entities do take action, they may choose to limit what their professionals can do.

MS. BEHR noted that she had not reviewed the regulations. However, she pointed out that there is always the ability to monitor for professional misconduct. If [pharmacists] didn't use their license appropriately, the board can always sanction them for inappropriate professional conduct, which the board must define. "So, there's two pieces to this. One is: the go forth for the future and then the second is: if you don't have a regulation in action, can the board take action on their existing regs for someone acting inappropriately outside the scope of their license?"

CHAIR McGUIRE pointed out that the Alaska Medical Association takes the position that it doesn't have the statutory authority to adopt these regulations.

MS. REARDON explained that DOL will review whether this regulation has the statutory authority to allow [the collaborative agreement] to go forward. Ms. Reardon suspected that DOL would review whether the statutes for pharmacists, dentists, and doctors allow [collaborative agreements]. She surmised that [DOL would also review] whether this collaborative agreement would amount to a delegation of the practice of medicine or dentistry. Ms. Reardon said that in her view that it wasn't clear that [a collaborative agreement] is a delegation of the practice of dentistry or medicine.

TAPE 01-2, SIDE A

Number 0030

REPRESENTATIVE JAMES said that it seems that there is going to be some decision-making that will be done by the pharmacist and thus would seem to be a delegation of decision-making. She didn't believe that [as many people] would get the flu shot if they had to go to the doctor to do so. However, she expressed concern with treating diabetics. She expected that the protocol for diabetic treatment at a pharmacy would be specific to that diabetic. This could be the case in other treatments, such as the monitoring of blood work, cholesterol, et cetera. However, she didn't expect that this would give a pharmacist a "blank check." Therefore, Representative James wanted to be sure that the regulations don't allow a physician to spread his disliked cases to the pharmacist. She emphasized the need to ensure that everyone in Alaska receives the best medical care possible.

Number 0266

MS. REARDON remarked that she could imagine a reading of these regulations that said [the collaborative agreement] isn't a delegation because the protocol could be perceived as a prescription. It could be said that the pharmacist is administering or distributing the physician's prescription.

REPRESENTATIVE JAMES commented that she could support that.

CHAIR McGUIRE noted her support of that also. However, she pointed out that pharmacists have dependent prescriptive authority and thus there could be a legal challenge.

REPRESENTATIVE HAYES reiterated that although there are no [collaborative agreement] regulations, this is the current practice and there has yet to be a lawsuit.

MS. REARDON agreed, but pointed out that "sometimes you think more when it gets on top of the table." What people are doing will be written down [in the regulations] and may lead to questions.

Number 0416

BARRY CHRISTENSEN, Pharmacist, testified via teleconference. He informed the committee that he was the president of the Alaska Pharmaceutical Association when the last Pharmacy Practice Act statutes were revised in 1996/1997. He remarked that those statutes were modeled after the National Association of Boards and Pharmacy Statute Guidelines. Alaska's statutes mirror the statutes of most of the other states, specifically the 30 states that have protocol-type agreements. Thus, Mr. Christensen expressed concern that [without these collaborative agreement regulations] Alaskan pharmacists are not the same as pharmacists in other states.

MR. CHRISTENSEN informed the committee of a management agreement that is occurring on a national level. This management agreement deals with a drug for treating patients that are resistant to typical schizophrenic drugs. This drug requires that the patient have his/her white blood count taken every one to two weeks in order to ensure that the drug isn't adversely affecting the body's ability to produce white blood cells. The drug is dispensed with an agreement between the pharmacist, the physician, and the drug manufacturer that the pharmacist will have the lab values from the patient's last blood draw in order to ensure that the patient's white blood count is over the

acceptable level in order for the pharmacist to dispense the drug. Mr. Christensen stated that this is an example of [a collaborative agreement] that is already occurring and would be validated by the adoption of the proposed regulations.

CHAIR McGUIRE said that she would appreciate continued contact with Mr. Christensen on the aforementioned management agreement.

ADJOURNMENT

There being no further business before the committee, the Joint Committee on Administrative Regulation Review meeting was adjourned at 11:21 a.m.