Approved: February 14, 1995

MINUTES OF THE HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES.

The meeting was called to order by Chairperson Carlos Mayans at 1:30 p.m. on February 9, 1995 in Room 423-S of the State Capitol.

All members were present.

Committee staff present: Norman Furse, Revisor of Statutes
Bill Wolff, Legislative Research Department
Lois Hedrick, Committee Secretary

Conferees appearing before the committee:
Tom Hitchcock, Executive Secretary, Kansas Board of Pharmacy
Bob Williams, Executive Director, Kansas Pharmacists Association
Robert D. Haneke, Pharmacist, Stafford
Stephen L. Smith, Pharmacist, Hiawatha
Jerry Slaughter, Executive Director, Kansas Medical Society
Harold Riehm, Executive Director, Kansas Association of Osteopathic Medicine
Lawrence T. Buening, Jr., Executive Director, Kansas Board of Healing Arts

Others attending: See Guest List, Attachment 1.

The minutes of the meeting held on February 7, 1995 were approved.

HB 2216 - Pharmacists' participation in the management of patient's drug therapy

Chairperson Mayans opened the hearing on the bill, asking the proponents to speak first.

Tom Hitchcock, Executive Secretary for the Board of Pharmacy, testified in support of the bill, stating that it would allow a pharmacist to enter into written protocols with physicians and participate in the management of patients drug therapy programs. The bill would allow the Board to promulgate regulations to implement this activity (see Attachment 2).

Bob Williams, Executive Director of the Kansas Pharmacists Association, as a proponent of the bill, offered testimony (see Attachment 3) to address some issues predominant in considering whether to allow pharmacists, under written protocols with physicians, to participate in the management of drug therapy programs. Mr. Williams indicated that because of concerns expressed regarding liability exposure, he had contacted Ken Baker, an attorney with Pharmacists Mutual (liability insurance carrier for most of the pharmacists in Kansas), to obtain his written statement. The statement has been distributed to the members, see Attachment 4. Mr. Williams described the considerations they follow in defining liability in the changing practices of pharmacists. Mr. Williams also indicated that it is important that if this bill is enacted, that the Board of Pharmacy be given the oversight responsibility and the additional duties and rights be a part of the Pharmacy Act (see Attachment 5).

Robert D. Haneke, Pharmacist from Stafford, testified in support of **HB 2216**. His testimony described the arrangement he has via a written protocol with Dr. M.H.V. Strickland to establish an asthma and allergy clinic (see Attachment 6).

Stephen L. Smith, Pharmacist from Hiawatha, testifying in support of the bill, stated that authorizing physician-pharmacist protocols will benefit patients, physicians, pharmacists, reduce the overall costs of healthcare, and give better patient outcomes (see Attachment 7).

Chairperson Mayans opened the meeting to questions of the proponents. Representative Geringer asked why the bill was needed. Mr. Hitchcock replied that it is to give statutory authority for written protocols between two healthcare professionals. It will legalize what some are doing already.

Representative Morrison questioned the pupose of the bill. Mr. Williams said the purpose is to establish authority in the Pharmacy Act. Prescriptive authority has already been given Physician Assistants and

ARNP's. Representative Morrison wondered if those pharmactists participating in written protocols at the present might be considered as practicing medicine without a license. Mr. Williams replied that the physician can delegate responsibility under the "Captain of the Ship" doctrine.

Representative Freeborn asked Mr. Haneke how this would save money; what were his charges. Mr. Haneke stated charges are based on the amount of time spent--about $1 a minute. Some third party payors pay the charge; some do not. The physician initiates the plan of treatment, and the pharmacist (under protocol) will oversee the effects of the drugs prescribed.

Chairperson Mayans asked Mr. Haneke if his re-evaluation of a drug prescribed to a patient is actually a diagnosis. Mr. Haneke said the physician makes the diagnosis and determines the therapy program, and he (as the pharmacist under protocol) may adjust the dosage or add a secondary agent to control the condition, which is an assessment and is addressed in the protocol.

The hearing was then opened for the opponents testimony.

Jerry Slaughter, Executive Director of the Kansas Medical Society, testified that the Society could not support **HB 2216** for the same reasons the Society set forth in opposing prescriptive authority being given to ARNP's. He stated the bill represents a significant expansion of the scope of practice for pharmacists. The Society believes that unique practice arrangements can be worked out under existing law to accommodate what the pharmacists are seeking with this bill and suggested that before the committee acts on the bill, it may want to consider sending the bill to an interim committee for additional study (see Attachment 8).

Harold Riehm, Executive Director of the Kansas Association of Osteopathic Medicine, testified in opposition to **HB 2116** (see Attachment 9). He stated there was nothing in the proposal that the Association could wholeheartedly support; that prescribing is a critical part of the healthcare process, but cannot be separated from the overall milieu of total care. Mr. Riehm noted that the proposal appears to enhance cooperation, but may be disruptive. There are no requirements in the bill to require the pharmacist to report to the physician. How will the physician always know what changes were made under the protocol? He questioned the nature of a protocol: who dictates the contents, how many pharmacists and how many protocols? The question of restraining trade rises; how would patients select a pharmacist? He also noted the Association supports the use of protocols for ARNP's and Physician Assistants, but there is a rather substantial difference between them and pharmacists in that the nurses are familiar with the patient's health history and the diagnosis that led to the prescription.

Lawrence T. Buening, Jr., Executive Director of the Kansas Board of Healing Arts, testified in opposition to **HB 2216** (see Attachment 10). He stated that he had tried to be a "fence sitter" on this bill but believes that if the Legislature wishes to authorize individuals to engage in the practice of medicine and surgery, that statutory language should provide such authorization and be under the auspices of the State Board of Healing Arts, which is the entity that licenses individuals to practice medicine and surgery.

The hearing was opened for questions to the opponents.

Representative Freeborn asked how a physician determines the qualifications of a pharmacist. Jerry Slaughter stated the physician has the responsibility to determine that the pharmacist is capable to exercise good judgment. Mr. Slaughter reminded the committee that previous testimony heard regarding prescriptive authority for nurse practitioners set out serious allegations that protocols are being purchased and that the prescriptive authority was being requested in order to permit nurses to be competitive with physicians. Mr. Slaughter indicated the Medical Society intends to bring language to the committee that will eliminate the possibility of the sale of protocols.

Representative Rutledge asked Mr. Riehm if the Legislature passes this bill, would there be costs incurred by the Healing Arts Board and the Pharmacy Board. Mr. Riehm stated that violations and disciplinary actions would need to be defined in the rules and regulations issued by the boards and there would be some costs.

Representative Rutledge asked Mr. Slaughter if the Medical Society would have a problem in accepting this bill if it was enacted. Mr. Slaughter said no; but, in his view, it is not a violation now but believed the act should be amended with new specifications for the arrangement.

Representative Rutledge questioned Mr. Riehm as to the status of doctor-patient confidentiality. He replied there is a difference between nurse practitioners and pharmacists in that nurses have access to medical history and the reasons for the prescription; whereas the pharmacist would only have a narrow acquaintance with the patient.

Representative Merritt questioned the confidentiality aspect of the situation, saying a physician is precluded by law to pass information about HIV-positive patients. Would that transpose to pharmacists in handling their drug therapy? Mr. Slaughter said there are circumstances under which you are compelled to maintain complete confidentiality; and others which cause the information to be shared. He indicated the concerns raised in this hearing merit additional study.

Representative Gilmore asked Mr. Haneke about billing insurance companies for charges. He indicated that such bills are for diagnostic and cognitive services and that some insurance companies will pay for these charges.

Chairperson Mayans indicated that at the next meeting on Monday, the committee will consider introduction of bills and hear **HB 2246** (state board of pharmacy grounds for disciplinary actions, costs of proceedings and appointment of executive director).

The meeting was adjourned at 2:56 p.m.

The next meeting is scheduled for February 13, 1995.

HEALTH AND HUMAN SERVICES COMMITTEE
GUEST LIST
FEBRUARY 9, 1995

NAME	REPRESENTING
Tom Rickman	mms. Inc.
myrle myers	J+J
Kathy Kruse	Glaxo Inc
Don Lingsey	UTu
Tom Hitchcock	Bd. Pharmacy
Robert Hancke	Pharmacy
Steve Smith	Pharmacy
Betty Johnson	Dealing Pets
Lawrence J. Bunning	" "
JERRY SLAUGHTER	KS. MEDICAL SOCIETY
Rich Guthrie	Health Midwest
Tom Bruno	Allen + Assoc.
Barbara Belcher	Merck
Nathalie Schaal	KHA
Eugene Stephens	SRS/DMS
Bob Williams	Ks. Pharmacists Assoc
Rebecca Rice	KPhA
Michelle Peterson	PhRMA
BILL HOWELL	UPJOHN CO.

HOUSE H&HS COMMITTEE
2 - 9 - 1995
Attachment 1-1

HEALTH AND HUMAN SERVICES COMMITTEE
GUEST LIST
FEBRUARY 9, 1995

NAME	REPRESENTING
Nancy Zogleman	Pfizer
Jane Greene	Nurses Day
Tammara Capps	Bristol-Myers Squibb
Frank Caro, Jr.	Merck & Co. Inc.
Patti L Gulley	KSNA Day at Legislature
Linda Hawkins RN	KSNA
Jacci Jones	KSNA
Allison Peterson	KS Medical Society
Charles M Hampton Jr	KSNA
Charlotte Reaka	KSNA
Carla A Lee	FHSC
John Federico	Pete McGill & Assoc.
Mary Ellen Conlee	St Francis Reg. Med. Center
Heather Hull	Wichita State Univ
David Hanzlick	KS Dental Ass'n
Ron Hein	Hein, Ebert & Weir, Chtd

Kansas State Board of Pharmacy

LANDON STATE OFFICE BUILDING
900 JACKSON AVENUE, ROOM 513
TOPEKA, KANSAS 66612-1231
PHONE (913) 296-4056
FAX (913) 296-8420

STATE OF KANSAS

BILL GRAVES
GOVERNOR

TOM C. HITCHCOCK
EXECUTIVE SECRETARY/DIRECTOR

DANA W. KILLINGER
BOARD ATTORNEY

HOUSE BILL 2216
COMMITTEE ON HEALTH AND HUMAN SERVICES
THURSDAY, FEBRUARY 9, 1995

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE, MY NAME IS TOM HITCHCOCK AND I SERVE AS THE EXECUTIVE SECRETARY FOR THE BOARD OF PHARMACY. I APPEAR BEFORE YOU TODAY ON BEHALF OF THE BOARD IN SUPPORT OF HB 2216.

THIS BILL WOULD NOT CHANGE THE PRACTICE OF PHARMACY, BUT WHAT IT WOULD DO IS ALLOW A PRACTITIONER AND THE PHARMACIST, AS THE MOST ACCESSIBLE MEMBER OF THE HEALTH CARE TEAM, TO ENTER INTO A WRITTEN PROTOCOL WITH EACH OTHER. SUCH WOULD STATE THE PRACTITIONER AS THE "RESPONSIBLE PRACTITIONER" OR THE CAPTAIN OF THE SHIP AND ALLOW THE PHARMACIST TO PARTICIPATE IN THE MANAGEMENT OF A PATIENT'S DRUG THERAPY AS AUTHORIZED, DELEGATED, AND LIMITED BY THE WRITTEN PROTOCOL. THE BILL WOULD ALSO ALLOW THE BOARD OF PHARMACY TO PROMULGATE REGULATIONS TO IMPLEMENT THIS ACTIVITY.

TODAY SUCH ACTIVITY IS ALLEGEDLY NOT PROHIBITED BY THE PHARMACY ACT OR THE HEALING ARTS ACT, BUT THE CURRENT LAW DOES NOT ADDRESS A WRITTEN PROTOCOL BETWEEN A PHARMACIST AND PHYSICIAN. THIS IS NEEDED AND SHOULD BE IMPLEMENTED WITH PROPER CONTROLS WHICH WOULD ASSIST THE PATIENT IN THE MANAGEMENT OF THEIR DRUG THERAPY.

THEREFORE, THE BOARD OF PHARMACY RESPECTFULLY REQUESTS THE **FAVORABLE PASSAGE OUT OF COMMITTEE OF HB 2216**.

THE KANSAS PHARMACISTS ASSOCIATION
1308 SW 10TH STREET
TOPEKA, KANSAS 66604
PHONE (913) 232-0439
FAX (913) 232-3764

ROBERT R. (BOB) WILLIAMS, M.S., C.A.E.
EXECUTIVE DIRECTOR

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

FEBRUARY 9, 1995

HOUSE Bill 2216

My name is Bob Williams. I am the Executive Director of the Kansas Pharmacists Association. Thank you for the opportunity to address the committee regarding House Bill 2216.

Pharmaceutical Care and Disease Management. Pharmaceutical care is defined as: ..."the responsible provisions of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes are cure of disease, elimination or reduction of a patient's symptomatology; arresting or slowing of a disease process; or preventing a disease symptomatology."

We are rapidly moving into an era of "disease management." Historically, health care has been a series of isolated components--hospital services and costs, physician services and costs, laboratory services and costs, pharmaceuticals and costs, and so on. By contrast, disease management grabs hold of the entire health care system, blurring the boundaries where hospital care meets physicians, pharmaceuticals, laboratories and consumer satisfaction. It involves systematic bites of problem areas that are high in volume, frequency and cost; diseases that are medication intensive and have been shown to respond to intervention. Some examples would include asthma, diabetes, hypertension, ischemic heart disease and hyperlipidemia.

Pharmacists are capable of offering quality patient care in assessing, monitoring and modifying medication therapies that ultimately produce improved health care quality in

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addition to reductions in health care costs. To achieve these improved outcomes, pharmacists are willing to move beyond the passive dispensing role to being fully focused on patient management skills for the purpose of demonstrating superior patient outcomes beyond the cost of the product.

Education. In regards to disease management, a pharmacist is trained to solve and prevent drug related problems, to provide continuity of care for patients leaving the hospital and doctors offices and they can contribute (and are contributing) by assuring that the physician's target goals are achieved by making sure the patient's therapy is as successful as possible. The pharmacy curriculum at Kansas University includes 76 credit hours of training in drugs and their effects on the human body. This includes 18 hours of clerkships in hospital externships and community based externships. There is an additional 50 credit hours in biology, chemistry, microbiology, mammalian physiology, health care management, societal aspects of pharmacy and pharmacy law. (See attached.) In addition pharmacists must obtain 15 hours annually of continuing education for re-licensure. As a matter of fact the individual who teaches the ARNP "Applied Drug Therapy" course at KU is Mike Oszko, a pharmacist who practices at the KU Medical Center. Clearly pharmacists have extensive training and are well qualified to actively participate in a patient's drug therapy under written protocols.

Quality Assurance. The delegation of prescriptive authority to pharmacists has been successfully applied in acute care, long term care, and ambulatory care settings. Pharmacists have been delegated prescriptive authority under protocol extensively in public health and military settings.

No greater quality control point exists than that associated with the delegation of authority of an individual practitioner's license. A physician (or physician group) must have the utmost confidence in the skills of any individual with whom they are willing to share licensed responsibility. Likewise, a pharmacist must be confident that the physician

/ho he is delegating authority is competent to assess his skill level in this specific area. The pharmacist must demonstrate appropriate knowledge and competence to the physician who is delegating authority prior to accepting such responsibility. Pharmacists will need to maintain continued competence to meet the standards of practice that have been defined.

Liability. A number of you have expressed concerns regarding liability exposure when a health care provider practices under written protocols. I invited Ken Baker, an attorney with Pharmacists Mutual which covers most of the lability insurance for pharmacists in Kansas, to testify at today's hearing. Unfortunately Ken was unable to make it. However, he has submitted a written statement. Ken has also asked me to let you know that he would welcome any phone calls should anyone have any questions.

As Ken points out, in Kansas we have individual liability rather than joint and severable liability. What that means is that in Kansas, a jury would proportion negligence based on liability rather than that proportion of negligence being based on some predetermined factor.

Liability exposure depends on items contained in the protocol. The protocol must be very specific. I have attached a listing of elements we believe are important to be included in written protocols.

Conclusion. Pharmacists are recognized as expert health care professionals who have the skill and commitment to help patients achieve the best possible health outcomes when drug therapy management is required. Most community pharmacists enjoy a positive working relationship with the prescribing physicians in their communities. With health care reform moving in the direction of capitation, physicians will need to minimize office visits. Pharmacists can help especially with high risk patients by improving compliance, disease management and quality of life.

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The Healing Arts Act does sanction and allow physicians to delegate certain functions to mid level practitioners under the so-called "Captain of the Ship" doctrine. Because physicians can currently enter into a protocol arrangement, the Kansas Medical Society contends that there is no need for House Bill 2216. While the Board of Healing Arts may sanction and allow physicians to enter into these kinds of arrangements with pharmacists, the Board of Pharmacy does not have statutory authority to regulate or monitor these protocol arrangements. The Kansas Pharmacists Association believes House Bill 2216 is necessary, not only for liability exposure issues for pharmacists practicing under these arrangements in Kansas, but to protect the patients as well.

We respectfully request your support of House Bill 2216.

DRUG PRODUCT QUALITY ReviewW
A PUBLICATION OF THE USP PRACTITIONERS' REPORTING NETWORK℠

No. 44

EASY BREATHING

Have you, as a practitioner, ever wondered if your patients are relaying accurately their experiences with inhalers? Are you unsure whether or not the inhaler is being used correctly? Are you exasperated when patients say they only got 100 sprays instead of the labeled 200 doses, that it tastes funny this time, or that they're not getting the expected relief?

Experimental work on albuterol metered-dose inhalers by the Canadian Health Protection Branch (CHPB) (the equivalent of the U.S. Food and Drug Administration) shows that the amount of drug in a dose from this metered-dose inhaler (MDI) product depends on how much time has lapsed since the preceding dose and the position in which the MDI has been stored. This study found that the drug content of single sprays of albuterol MDI ranged between 23% and 208% of the label claim. Additional evidence from this study suggests that initial sprays from a new canister had a higher drug content than the final doses emitted from that same canister. Single, unprimed doses (doses taken 4 or more hours following the last spray) from individual canisters stored with the valve in the upright position and activated after 4 or 16 hours averaged a higher drug content than single, unprimed doses from canisters stored with the valve down. Primed sprays (i.e., those sprays that were taken within minutes of a previous spray), whether stored with the valve up or the valve down, contained a mean of 92% of labeled drug content. These results are reflected in reports received through the USP Practitioners' Reporting Network℠ (USP PRN℠) in the accompanying table.

Another study by the CHPB examined cromolyn sodium metered-dose inhalers. The results of this study indicated that many of the doses tested were consistently outside USP dosage uniformity limits. The amount of active ingredient contained in the doses tested varied between each canister and also varied within individual canisters tested.

The May–June 1994 *Pharmacopeial Forum* (*PF*) contains two *Stimuli* articles from the USP Advisory Panel on Aerosols suggesting improvements in standards that specifically address new aerosol products and continuing problems with aerosols. Redrafts of two mandatory *USP* general tests chapters, *Aerosols* ⟨601⟩ and *Uniformity of Dosage Units* ⟨905⟩, have been recommended. The redrafts formulate new tests, modify existing ones, and then designate those tests that are specific only to pressurized aerosols intended for topical application, metered-dose inhalers, or dry powder inhalers. In addition, the panel recommends renaming the chapter *Aerosols* ⟨601⟩ to *Aerosols, Metered-dose Inhalers, and Dry Powder Inhalers* ⟨601⟩.

While the Advisory Panel recommendations address changing the physical characteristics of aerosol dosage delivery, one Panel member recommends the addition of a supplementary test to chapter ⟨601⟩ entitled *Dose Uniformity Over the Entire Contents.* Lack of uniform therapeutic delivery is a real concern to patients and was cited also in the CHPB study. The author of this latest article, which appears in the May–June 1994 *PF*, recommends that inhalers be tested for drug content per dose using dose collection schedules that imitate how patients actually use the product.

The Advisory Panel is seeking comments and suggestions prior to making its final recommendations, which would be subject to review, revision, and acceptance by the USP Subcommittee on Excipients prior to being added to *USP-NF.* Once new requirements are adopted and made official, all manufactured aerosol products would be required to conform.

In the meantime, health care practitioners can help ensure the proper use and proper storage of inhalers by counseling patients appropriately. Proper storage of inhalers in an upright position should be emphasized, especially if the patient's scheduled dose is a single, unprimed spray. Storage at the proper temperature is also important. For example, carrying an aerosol canister in a purse, pocket, backpack, suitcase, or storing the canister in the glove compartment of a car during the summer could expose the product to compromising temperatures. Storage of the inhaler in a prone position may result in a less than effective dose. An unusual taste may indicate that the inhaler is delivering nonactive ingredients, such as propellants in a concentration other than that expected.

While counseling the patient, it should be recommended that the inhaler system be primed if any significant length of time elapses between doses. The next dose of a medication to be delivered to a patient is actually contained in a reservoir. Priming will ensure that a full dose is contained in the reservoir so the patient will not be underdosed.

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Finally, thorough counseling should reveal if the patient understands the information in the patient package insert and if the patient is using the product correctly. Additional counseling at the time of refill may be necessary in order to reinforce proper inhalation techniques, handling, and storage.

The following incidents were reported through the USP PRN between April 1993 and May 1994. The abstracted information represents problems and complaints experienced with inhalers.

Table of DPPR Reports on Inhalers

Inhaler	Reported Incident
Albuterol inhaler	The aerosol mechanism does not work properly and continues to discharge the product. The container does not deliver a uniform amount of medication. The container does not hold the labeled number of doses, or it feels empty before any usage. The latest refill is not therapeutically effective. The valve on a full canister will not activate.
Beclomethasone dipropionate inhaler	Only 20 inhalations are emitted from a container that should deliver 200 inhalations. There was one complaint about getting only two doses from each of the past two canisters before the inhaler quits working. The mechanism does not work properly and continues to discharge medication, even after pressure is removed from the valve, emptying the container. Two actuations are required per dose; the second actuation does not always work.
Metaproterenol sulfate inhaler	The latest refill does not provide any therapeutic effect and tastes "fishy." The latest refill is therapeutically ineffective.
Terbutaline sulfate inhaler	There are two instances of a metallic taste in mouth, burning in lungs, and worsening of asthma symptoms while using the product. The condition improves upon replacement of inhaler. The last two refills do not provide the labeled number of doses.
Flunisolide inhaler	Two different canisters, dispensed one right after the other, do not contain the labeled number of doses. In another case, the latest refills deliver only 19 and 68 respective doses; this is an ongoing problem. The inhaler is reported to deliver a super-potent dose.
Pirbuterol acetate inhaler	The inhaler works sporadically and is not reliable.
Nedocromil sodium inhaler	The device malfunctions and sprays mist inside the chamber instead of via the valve to the patient.
Triamcinolone acetonide inhaler	The device needs to be actuated twice in order to get one inhalation.
Ipratropium bromide inhaler	The device delivers medication inconsistently; medication loses its effectiveness after 10 days of regular use. The device delivers only 100 of the labeled 200 inhalations.

To report similar problems with drug products or to receive further information, call the USP Practitioners' Reporting Network℠ at 1-800-4-USP PRN.

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Prepharmacy Curriculum and Professional Program

Courses are listed with KU numbers and titles.

	Fall	
Year 1	ENGL 101 Composition	3
	BIOL 104 Principles of Biology Lecture	3
	BIOL 106 Principles of Biology Laboratory	2
	CHEM 184 Foundations of Chemistry I	5
	[1]MATH 115 Calculus I (3) or	
	[2]General studies (3)	3
		16
Year 2	CHEM 624 Organic Chemistry I Lecture	3
	CHEM 625 Organic Chemistry I Laboratory	2
	BIOL 400 Microbiology Lecture	3
	BIOL 402 Microbiology Laboratory	2
	[2]General studies	6
		16-17

	Spring	
	ENGL 102 Composition and Literature	3
	CHEM 188 Foundations of Chemistry II	5
	[1]MATH 115 Calculus I (3) or	
	[2]General studies (3)	3
	[2]General studies	6
		17
	CHEM 626 Organic Chemistry II Lecture	3
	CHEM 627 Organic Chemistry II Laboratory	2
	BIOL 726 Mammalian Physiology Lecture	4
	BIOL 727 Mammalian Physiology Laboratory	1
	COMS 150 Personal Communication	3
	[2]General studies	3
		16

Professional Program

Year 3	BIOL 600 Biochemistry Lecture	4
	BIOL 601 Biochemistry Laboratory	2
	P&TX 624 Pharmacology I	4
	PHCH 514 Pharmaceutics I	3
	PHCH 515 Pharmacy Calculations	1
	PHPR 571 Pharmacy Practice I	1
	MDCM513 Introduction to Drug Assay	3
	PHPR 200 Pharmacy Orientation	1
		18-19
	P&TX 635 Pharmacology II	4
	PHCH 624 Pharmaceutics II	4
	PHCH 621 Pharmaceutics II Laboratory	1
	MDCM 624 Organic Medicinal Agents I	4
	PHPR 581 Pharmacy Practice II	1
	HSCA 618 The Societal Aspects of Pharmacy	3
		17
Year 4	P&TX 513 Pathophysiology	3
	PHCH 654 Pharmaceutics III	3
	PHCH 631 Pharmaceutics III Laboratory	1
	MDCM 635 Organic Medicinal Agents II	5
	HSCA 613 Financial Management	3
	[3]Pharmacy electives	3
		18
	P&TX 623 Toxicology	2
	PHPR 645 Therapeutics	6
	PHPR 621 Pharmacy Law	2
	[4]PHPR 672 Dispensing Laboratory	2
	P&TX 600 Pharmacy Biotechnology	3
	[3]Pharmacy electives	3
		18
Year 5	PHPR 675 Pharmacy Practice III	5
	[4]PHPR 672 Dispensing Laboratory	2
	PHPR 673 Health Care Management	3
	[3]Pharmacy electives	4
		14
	PHPR 676 Clinical Clerkship	6
	PHPR 686 Hospital Externship	6
	PHPR 696 Community Externship	6
		18

Physics Requirement. It is recommended that students include physics in their college preparatory curricula. A grade of B or better in high school physics will fulfill the physics requirement for the School of Pharmacy. For those students who do not take physics in high school, the course PHSX 111 (3 credit hours) or equivalent is required. However, these hours will not count toward graduation.

[1]The mathematics requirement is MATH 115 Calculus. Any prerequisite mathematics courses taken before the student is eligible to take MATH 115 will not be counted as hours toward graduation.

[2]The B.S. degree requires 30 hours of general studies courses. Twelve of these 30 hours are the required 6 hours of English, 3 hours of Calculus, and 3 hours of Personal Communications. The remaining 18 hours must include 9 hours of humanity or social science courses (examples are history, literature, art appreciation or music appreciation, economics, sociology, psychology, political science, and anthropology). The balance of 9 hours are elected by the student subject to the limitations stated below. Most regular college courses other than physical or biological sciences are acceptable. The only types of courses the school does not accept are activity courses in the arts or physical education, courses in other professional schools (e.g., engineering) unless these clearly relate to the practice of pharmacy (e.g., business courses), and more than 6 hours of courses in military science. A student does *not* need 30 hours of general studies to enter the school; rather, these are required to complete the B.S. degree. It is to the student's advantage to acquire as many of these hours in the prepharmacy portion of the curriculum as possible.

[3]A minimum of 7 hours of pharmacy elective courses is required. The following courses are representative of the elective courses available.

- MDCM 692 Problems in Medicinal Chemistry
- PHCH 692 Clinical Pharmacokinetics
- PHCH 694 Problems in Pharmaceutical Chemistry
- P&TX 684 Advanced Topics in Drug Therapy
- PHPR 425 Pharmacy Practice for the Geriatric Patient
- PHPR 602 Controversies in Pharmacy Practice

[4]May be taken in fourth year spring semester or fifth year fall semester.

Pharmacists' Professional Services, Related to Traditional Drug Therapy Management

1. *Patient Assessment.* The pharmacist assesses the patient's health condition as it relates to drug therapy by reviewing routine vital signs (for example, an assessment of anti-hypertensive drug therapy by taking the patient's blood pressure).

2. *Patient Counseling.* After determining the most appropriate medication for the patient, the pharmacist counsels the patient on how to take medications, potential side effects, and dosage. In some cases, extended patient counseling is necessary due to the complexity of a patient's drug-related problem(s). The pharmacist gives patients personalized information about their ailments and the medications to make certain that they understand the drug regimen. The pharmacist also recommends certain changes in life-style and diet, if necessary, to hasten recovery from or prevent an illness.

3. *Patient Education and Training.* The pharmacist trains and educates the patient beyond counseling when the drug prescribed has complex usage instructions or complex administration (for example, extended education or training provided so patients appropriately use inhalers or drugs they must inject themselves).

   Patient education and training may also require pharmacists to offer patients written information on their specific drug regimens.

4. *Follow-up and Compliance Monitoring.* The pharmacist follows up with the patient, either by phoning or setting up an appointment, to ensure compliance with the drug therapy. Follow-up is necessary to ensure that patients comply with the drug regimen.

5. *Change of Dosage.* The pharmacist changes the drug dosage, form, or duration with prescriber authorization due to inappropriate or incorrect dose or dosage regimen prescribed.

6. *Discontinuation of Medication.* The pharmacist discontinues the patient's medication with prescriber authorization.

7. *Decision Not to Dispense.* The pharmacist does not dispense the medication after contact with and the authorization of the prescriber.

8. *Generic Product Selection.* The pharmacist dispenses a generic drug when the prescriber recommends a brand-name drug for which there is an appropriate generic equivalent.

9. *Therapeutic Interchange.* The pharmacist dispenses a therapeutically equivalent drug with prescriber authorization.

   The pharmacist-physician consultation that can lead to the physician's approval of an equally effective but less costly therapeutically equivalent medication should be part of a cost-effective outpatient pharmacy services benefit. Clear protocols and guidelines developed jointly by pharmacists and physicians must *responsibly* manage the use of drugs.

10. *Case Management.* The patient is referred to a pharmacist by a physician or a health plan for case management of a patient's drug therapy through a customized care program developed by the pharmacist, the physician, and/or the health plan.

    Patients with chronic illnesses—asthma, hypertension, and diabetes, among others—require thorough and ongoing monitoring of their conditions and drug therapy. For example, pharmacists perform blood glucose screening for diabetic patients. The medications used to treat such ailments, if used improperly by the patients, are more likely to cause severe health problems than medications used for treatment of most other conditions.

11. *Nonprescription Drug Therapy Interventions.* The pharmacist recommends a nonprescription medication for the patient based on symptoms and problems presented and counsels the patient on its proper use. The pharmacist can promote cost-effective, quality care by helping consumers choose appropriate nonprescription medications.

Core elements of the protocol should include the following:

a. A written statement specifying that prescriptive authority of the stated physician or physician group practice is delegated to the pharmacist(s).
b. The prescribing activities that are delegated must be clear to both the physician(s) and pharmacist(s).
c. The scope of practice for the pharmacist should be defined for each protocol.
d. Limits are identified beyond which the physician must be contacted in order for the pharmacist to proceed.
e. Procedures are clearly defined for documenting the pharmacist's practice decisions and care provided.
f. A time limit for each protocol arrangement should exist, beyond which the protocol should be reviewed and revised, if necessary.
g. A system should exist in which the physician and pharmacist periodically evaluate the quality of care provided to patients who are treated using the protocol treatment guidelines.
h. Pharmacists must demonstrate and maintain knowledge and competence needed to meet appropriate standards of practice.

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Pharmacists Mutual *Companies*

- Pharmacists Mutual Insurance Company
- Pharmacists Life Insurance Company
- Pro Advantage Services, Inc.

February 08, 1995

Robert R. Williams, M.S., C.A.E.
Executive Director
Kansas Pharmacists Association
1308 SW 10th Ave.
Topeka, KS 66604-1299

IN RE: Pharmacist Prescribing by Protocol

Dear Bob,

You asked that I address several issues relating to proposed legislation granting Kansas pharmacists prescriptive authority pursuant to physician protocol. We at Pharmacists Mutual began looking at this question in 1993 and to a greater extent in 1994. In 1993 we began work on a project to redefine covered pharmacy services in our insurance policies. We did this in recognition of changes occurring in the practice of pharmacy and proposed legislation in many of the states in which we write professional pharmacy insurance coverage.

The state of South Dakota recognizes prescriptive protocol agreements between pharmacists and physicians as part of its pharmacy practice act as does New Mexico. We are licensed and do business in both of these states. In neither of these states have we significantly increased our premium. After studying the question we concluded there was some increased risk, but it was not considerable. Our new coverage definition for "Pharmacy Services" was adopted in 1994 and filed in all our states. During this period there was little or no increase in premium because of these filings. A copy of our Pharmacy Services endorsement to our commercial policy is attached. Please note paragraph (b) of the definition. We use the same definition in our individual policies. Through one or both of these policies, I estimate we insure 75% of the retail pharmacists in Kansas.

As to the division of liability between the physician and the pharmacist working under the physician's prescriptive authority by protocol, each professional has separate duties. While there could be some overlap in duty, each professional would have separate liability for breach of duty. In order to prevail in an action for negligence the plaintiff must prove defendant's duty and breach of duty was directly linked to the plaintiff's damages. Through written protocol the pharmacist takes on the duty to follow the steps outlined in the agreement with the physician. The pharmacist must then react according to the dictates of the protocol.

The pharmacist assumes risk management duties regarding the patient's medication. If the pharmacist is negligent in these duties, he or she may be liable. This is essentially the duties of pharmaceutical care now advocated as part of the pharmacist's role throughout the United States. Unless the pharmacist is the employee of the physician vicarious liability is unlikely. Any negligence by the pharmacist in carrying out the protocol duties is borne by the pharmacist, not the physician. For the physician to be held liable, absent vicarious liability, it would be

Highway 18 West • P.O. Box 370, Algona, Iowa 50511 • Phone: (515) 295-2461

necessary for the physician to be negligent in selection of the pharmacist or in dictating an improper protocol. These are duties of the physician.

Under protocol the roles of medication risk management and medication risk assessment are divided. The pharmacist, trained in use and action of drugs on the body, becomes a medication risk manager. Once the drug, or class of drug, is selected by the physician based upon the physician's diagnoses, the pharmacist can now work with the patient to assure best use and effect of the selected drug or class. The pharmacist may select a dosage depending on the effects or side effects on the individual patient or may select specific drugs within a limited range of choices outlined in the protocol. The specific drug selected may depend upon side effects present or other criteria set forth in the protocol. Because the pharmacist assumes only medication risk management duties he or she would not be liable for medication risk assessment decisions. It remains the physician's duty to diagnose and assess the risk of drug verses surgical or other alternate treatment or of drug class selection. The pharmacist would not be liable for physician errors in diagnoses or assessment of risk absent an independent duty.

It is important that if the pharmacist is given additional duties and rights, they be part of the Kansas pharmacy practice act. This is necessary not only for legal definitions such as ours, but also to assure oversight authority through the Board of Pharmacy. The pharmacy practice act sets forth rights, duties and responsibilities of pharmacists and defines the practice of pharmacy. Such a definition should be complete.

Sincerely,

Kenneth R. Baker, R.Ph., J.D.
Vice President, General Counsel
Direct Extension: 273

This endorsement changes
the Commercial Liability Coverages
provided by this policy
—Please Read This Carefully—

PHARMACY PROFESSIONAL LIABILITY COVERAGE

The Commercial Liability Coverage of this policy is amended as shown below:

EXCLUSIONS THAT APPLY TO ALL COVERAGES

Exclusion 3. does not apply to professional liability arising out of the rendering or failure to render **Pharmacy Services.**

Pharmacy Services means:

(a) The interpretation, evaluation and dispensing of prescription orders.
(b) Participation in drug and device selection (including, where permitted by state or federal law, prescribing by protocol or agreement or the prescribing of legally recognized pharmacist-class of drugs or devices).
(c) Drug administration by a registered pharmacist where permitted by state law as a part of the practice of pharmacy.
(d) Drug regimen reviews.
(e) Drug or drug-related research.
(f) Medication consulting; patient counseling; and those acts or services necessary to provide pharmaceutical care.
(g) The responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices).
(h) Proper and safe storage of drugs and devices.
(i) Maintenance of proper records for drugs and devices.
(j) All other services of a professional nature usually and customarily performed by a registered pharmacist or qualified pharmacy intern. This includes but is not limited to those professional services customarily performed by a retail pharmacist, hospital pharmacist, consultant pharmacist, clinical pharmacist, long term care pharmacist, or nuclear pharmacist.

The following exclusion is added:

We do not pay for **bodily injury** or **property damage** or **personal injury** or **advertising injury** caused by willful violation of a statute, ordinance, or regulation relating to **Pharmacy Services** by or with the knowledge or consent of an insured.

HOW MUCH WE PAY

The following is added to **How Much We Pay:**

For the coverage provided by this endorsement, any act or omission and all related acts or omission in the furnishing of **Pharmacy Services** to any one person is considered one occurrence.

4 - 3

THE KANSAS PHARMACISTS ASSOCIATION
1308 SW 10TH STREET
TOPEKA, KANSAS 66604
PHONE (913) 232-0439
FAX (913) 232-3764

ROBERT R. (BOB) WILLIAMS, M.S., C.A.E.
EXECUTIVE DIRECTOR

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

FEBRUARY 9, 1995

HOUSE Bill 2216

My name is Bob Williams. I am the Executive Director of the Kansas Pharmacists Association. Thank you for the opportunity to address the committee regarding House Bill 2216.

Pharmaceutical Care and Disease Management. Pharmaceutical care is defined as: ..."the responsible provisions of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes are cure of disease, elimination or reduction of a patient's symptomatology; arresting or slowing of a disease process; or preventing a disease symptomatology."

We are rapidly moving into an era of "disease management." Historically, health care has been a series of isolated components--hospital services and costs, physician services and costs, laboratory services and costs, pharmaceuticals and costs, and so on. By contrast, disease management grabs hold of the entire health care system, blurring the boundaries where hospital care meets physicians, pharmaceuticals, laboratories and consumer satisfaction. It involves systematic bites of problem areas that are high in volume, frequency and cost; diseases that are medication intensive and have been shown to respond to intervention. Some examples would include asthma, diabetes, hypertension, ischemic heart disease and hyperlipidemia.

Pharmacists are capable of offering quality patient care in assessing, monitoring and modifying medication therapies that ultimately produce improved health care quality in

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addition to reductions in health care costs. To achieve these improved outcomes, pharmacists are willing to move beyond the passive dispensing role to being fully focused on patient management skills for the purpose of demonstrating superior patient outcomes beyond the cost of the product.

Education. In regards to disease management, a pharmacist is trained to solve and prevent drug related problems, to provide continuity of care for patients leaving the hospital and doctors offices and they can contribute (and are contributing) by assuring that the physician's target goals are achieved by making sure the patient's therapy is as successful as possible. The pharmacy curriculum at Kansas University includes 76 credit hours of training in drugs and their effects on the human body. This includes 18 hours of clerkships in hospital externships and community based externships. There is an additional 50 credit hours in biology, chemistry, microbiology, mammalian physiology, health care management, societal aspects of pharmacy and pharmacy law. (See attached.) In addition pharmacists must obtain 15 hours annually of continuing education for re-licensure. As a matter of fact the individual who teaches the ARNP "Applied Drug Therapy" course at KU is Mike Oszko, a pharmacist who practices at the KU Medical Center. Clearly pharmacists have extensive training and are well qualified to actively participate in a patient's drug therapy under written protocols.

Quality Assurance. The delegation of prescriptive authority to pharmacists has been successfully applied in acute care, long term care, and ambulatory care settings. Pharmacists have been delegated prescriptive authority under protocol extensively in public health and military settings.

No greater quality control point exists than that associated with the delegation of authority of an individual practitioner's license. A physician (or physician group) must have the utmost confidence in the skills of any individual with whom they are willing to share licensed responsibility. Likewise, a pharmacist must be confident that the physician

who he is delegating authority is competent to assess his skill level in this specific area. The pharmacist must demonstrate appropriate knowledge and competence to the physician who is delegating authority prior to accepting such responsibility. Pharmacists will need to maintain continued competence to meet the standards of practice that have been defined.

Liability. A number of you have expressed concerns regarding liability exposure when a health care provider practices under written protocols. I invited Ken Baker, an attorney with Pharmacists Mutual which covers most of the lability insurance for pharmacists in Kansas, to testify at today's hearing. Unfortunately Ken was unable to make it. However, he has submitted a written statement. Ken has also asked me to let you know that he would welcome any phone calls should anyone have any questions.

As Ken points out, in Kansas we have individual liability rather than joint and severable liability. What that means is that in Kansas, a jury would proportion negligence based on liability rather than that proportion of negligence being based on some predetermined factor.

Liability exposure depends on items contained in the protocol. The protocol must be very specific. I have attached a listing of elements we believe are important to be included in written protocols.

Conclusion. Pharmacists are recognized as expert health care professionals who have the skill and commitment to help patients achieve the best possible health outcomes when drug therapy management is required. Most community pharmacists enjoy a positive working relationship with the prescribing physicians in their communities. With health care reform moving in the direction of capitation, physicians will need to minimize office visits. Pharmacists can help especially with high risk patients by improving compliance, disease management and quality of life.

-over-

The Healing Arts Act does sanction and allow physicians to delegate certain functions to mid level practitioners under the so-called "Captain of the Ship" doctrine. Because physicians can currently enter into a protocol arrangement, the Kansas Medical Society contends that there is no need for House Bill 2216. While the Board of Healing Arts may sanction and allow physicians to enter into these kinds of arrangements with pharmacists, the Board of Pharmacy does not have statutory authority to regulate or monitor these protocol arrangements. The Kansas Pharmacists Association believes House Bill 2216 is necessary, not only for liability exposure issues for pharmacists practicing under these arrangements in Kansas, but to protect the patients as well.

We respectfully request your support of House Bill 2216.

DRUG PRODUCT QUALITY ReviewW
A PUBLICATION OF THE USP PRACTITIONERS' REPORTING NETWORK℠

No. 44

EASY BREATHING

Have you, as a practitioner, ever wondered if your patients are relaying accurately their experiences with inhalers? Are you unsure whether or not the inhaler is being used correctly? Are you exasperated when patients say they only got 100 sprays instead of the labeled 200 doses, that it tastes funny this time, or that they're not getting the expected relief?

Experimental work on albuterol metered-dose inhalers by the Canadian Health Protection Branch (CHPB) (the equivalent of the U.S. Food and Drug Administration) shows that the amount of drug in a dose from this metered-dose inhaler (MDI) product depends on how much time has lapsed since the preceding dose and the position in which the MDI has been stored. This study found that the drug content of single sprays of albuterol MDI ranged between 23% and 208% of the label claim. Additional evidence from this study suggests that initial sprays from a new canister had a higher drug content than the final doses emitted from that same canister. Single, unprimed doses (doses taken 4 or more hours following the last spray) from individual canisters stored with the valve in the upright position and activated after 4 or 16 hours averaged a higher drug content than single, unprimed doses from canisters stored with the valve down. Primed sprays (i.e., those sprays that were taken within minutes of a previous spray), whether stored with the valve up or the valve down, contained a mean of 92% of labeled drug content. These results are reflected in reports received through the USP Practitioners' Reporting Network℠ (USP PRN℠) in the accompanying table.

Another study by the CHPB examined cromolyn sodium metered-dose inhalers. The results of this study indicated that many of the doses tested were consistently outside USP dosage uniformity limits. The amount of active ingredient contained in the doses tested varied between each canister and also varied within individual canisters tested.

The May–June 1994 *Pharmacopeial Forum* (*PF*) contains two *Stimuli* articles from the USP Advisory Panel on Aerosols suggesting improvements in standards that specifically address new aerosol products and continuing problems with aerosols. Redrafts of two mandatory *USP* general tests chapters, *Aerosols* ⟨601⟩ and *Uniformity of Dosage Units* ⟨905⟩, have been recommended. The redrafts formulate new tests, modify existing ones, and then designate those tests that are specific only to pressurized aerosols intended for topical application, metered-dose inhalers, or dry powder inhalers. In addition, the panel recommends renaming the chapter *Aerosols* ⟨601⟩ to *Aerosols, Metered-dose Inhalers, and Dry Powder Inhalers* ⟨601⟩.

While the Advisory Panel recommendations address changing the physical characteristics of aerosol dosage delivery, one Panel member recommends the addition of a supplementary test to chapter ⟨601⟩ entitled *Dose Uniformity Over the Entire Contents*. Lack of uniform therapeutic delivery is a real concern to patients and was cited also in the CHPB study. The author of this latest article, which appears in the May–June 1994 *PF*, recommends that inhalers be tested for drug content per dose using dose collection schedules that imitate how patients actually use the product.

The Advisory Panel is seeking comments and suggestions prior to making its final recommendations, which would be subject to review, revision, and acceptance by the USP Subcommittee on Excipients prior to being added to *USP-NF*. Once new requirements are adopted and made official, all manufactured aerosol products would be required to conform.

In the meantime, health care practitioners can help ensure the proper use and proper storage of inhalers by counseling patients appropriately. Proper storage of inhalers in an upright position should be emphasized, especially if the patient's scheduled dose is a single, unprimed spray. Storage at the proper temperature is also important. For example, carrying an aerosol canister in a purse, pocket, backpack, suitcase, or storing the canister in the glove compartment of a car during the summer could expose the product to compromising temperatures. Storage of the inhaler in a prone position may result in a less than effective dose. An unusual taste may indicate that the inhaler is delivering nonactive ingredients, such as propellants in a concentration other than that expected.

While counseling the patient, it should be recommended that the inhaler system be primed if any significant length of time elapses between doses. The next dose of a medication to be delivered to a patient is actually contained in a reservoir. Priming will ensure that a full dose is contained in the reservoir so the patient will not be underdosed.

Issued 10/94

Finally, thorough counseling should reveal if the patient understands the information in the patient package insert and if the patient is using the product correctly. Additional counseling at the time of refill may be necessary in order to reinforce proper inhalation techniques, handling, and storage.

The following incidents were reported through the USP PRN between April 1993 and May 1994. The abstracted information represents problems and complaints experienced with inhalers.

Table of DPPR Reports on Inhalers

Inhaler	Reported Incident
Albuterol inhaler	The aerosol mechanism does not work properly and continues to discharge the product. The container does not deliver a uniform amount of medication. The container does not hold the labeled number of doses, or it feels empty before any usage. The latest refill is not therapeutically effective. The valve on a full canister will not activate.
Beclomethasone dipropionate inhaler	Only 20 inhalations are emitted from a container that should deliver 200 inhalations. There was one complaint about getting only two doses from each of the past two canisters before the inhaler quits working. The mechanism does not work properly and continues to discharge medication, even after pressure is removed from the valve, emptying the container. Two actuations are required per dose; the second actuation does not always work.
Metaproterenol sulfate inhaler	The latest refill does not provide any therapeutic effect and tastes "fishy." The latest refill is therapeutically ineffective.
Terbutaline sulfate inhaler	There are two instances of a metallic taste in mouth, burning in lungs, and worsening of asthma symptoms while using the product. The condition improves upon replacement of inhaler. The last two refills do not provide the labeled number of doses.
Flunisolide inhaler	Two different canisters, dispensed one right after the other, do not contain the labeled number of doses. In another case, the latest refills deliver only 19 and 68 respective doses; this is an ongoing problem. The inhaler is reported to deliver a super-potent dose.
Pirbuterol acetate inhaler	The inhaler works sporadically and is not reliable.
Nedocromil sodium inhaler	The device malfunctions and sprays mist inside the chamber instead of via the valve to the patient.
Triamcinolone acetonide inhaler	The device needs to be actuated twice in order to get one inhalation.
Ipratropium bromide inhaler	The device delivers medication inconsistently; medication loses its effectiveness after 10 days of regular use. The device delivers only 100 of the labeled 200 inhalations.

To report similar problems with drug products or to receive further information, call the USP Practitioners' Reporting Network℠ at 1-800-4-USP PRN.

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Prepharmacy Curriculum and Professional Program

Courses are listed with KU numbers and titles.

	Fall		Spring	
Year 1	ENGL 101 Composition	3	ENGL 102 Composition and Literature	3
	BIOL 104 Principles of Biology Lecture	3	CHEM 183 Foundations of Chemistry II	5
	BIOL 106 Principles of Biology Laboratory	2	[1]MATH 115 Calculus I (3) or	
	CHEM 184 Foundations of Chemistry I	5	[2]General studies (3)	3
	[1]MATH 115 Calculus I (3) or		[2]General studies	6
	[2]General studies (3)	3		17
		16		
Year 2	CHEM 624 Organic Chemistry I Lecture	3	CHEM 626 Organic Chemistry II Lecture	3
	CHEM 625 Organic Chemistry I Laboratory	2	CHEM 627 Organic Chemistry II Laboratory	2
	BIOL 400 Microbiology Lecture	3	BIOL 726 Mammalian Physiology Lecture	4
	BIOL 402 Microbiology Laboratory	2	BIOL 727 Mammalian Physiology Laboratory	1
	[2]General studies	6	COMS 150 Personal Communication	3
		16-17	[2]General studies	3
				16
	Professional Program			
Year 3	BIOL 600 Biochemistry Lecture	4	P&TX 635 Pharmacology II	4
	BIOL 601 Biochemistry Laboratory	2	PHCH 624 Pharmaceutics II	4
	P&TX 624 Pharmacology I	4	PHCH 621 Pharmaceutics II Laboratory	1
	PHCH 514 Pharmaceutics I	3	MDCM 624 Organic Medicinal Agents I	4
	PHCH 515 Pharmacy Calculations	1	PHPR 581 Pharmacy Practice II	1
	PHPR 571 Pharmacy Practice I	1	HSCA 618 The Societal Aspects of Pharmacy	3
	MDCM513 Introduction to Drug Assay	3		17
	PHPR 200 Pharmacy Orientation	1		
		18-19		
Year 4	P&TX 513 Pathophysiology	3	P&TX 623 Toxicology	2
	PHCH 654 Pharmaceutics III	3	PHPR 645 Therapeutics	6
	PHCH 631 Pharmaceutics III Laboratory	1	PHPR 621 Pharmacy Law	2
	MDCM 635 Organic Medicinal Agents II	5	[4]PHPR 672 Dispensing Laboratory	2
	HSCA 613 Financial Management	3	P&TX 600 Pharmacy Biotechnology	3
	[3]Pharmacy electives	3	[3]Pharmacy electives	3
		18		18
Year 5	PHPR 675 Pharmacy Practice III	5	PHPR 676 Clinical Clerkship	6
	[4]PHPR 672 Dispensing Laboratory	2	PHPR 686 Hospital Externship	6
	PHPR 673 Health Care Management	3	PHPR 696 Community Externship	6
	[3]Pharmacy electives	4		18
		14		

Physics Requirement. It is recommended that students include physics in their college preparatory curricula. A grade of B or better in high school physics will fulfill the physics requirement for the School of Pharmacy. For those students who do not take physics in high school, the course PHSX 111 (3 credit hours) or equivalent is required. However, these hours will not count toward graduation.

[1]The mathematics requirement is MATH 115 Calculus. Any prerequisite mathematics courses taken before the student is eligible to take MATH 115 will not be counted as hours toward graduation.

[2]The B.S. degree requires 30 hours of general studies courses. Twelve of these 30 hours are the required 6 hours of English, 3 hours of Calculus, and 3 hours of Personal Communications. The remaining 18 hours must include 9 hours of humanity or social science courses (examples are history, literature, art appreciation or music appreciation, economics, sociology, psychology, political science, and anthropology). The balance of 9 hours are elected by the student subject to the limitations stated below. Most regular college courses other than physical or biological sciences are acceptable. The only types of courses the school does not accept are activity courses in the arts or physical education, courses in other professional schools (e.g., engineering) unless these clearly relate to the practice of pharmacy (e.g., business courses), and more than 6 hours of courses in military science. A student does *not* need 30 hours of general studies to enter the school; rather, these are required to complete the B.S. degree. It is to the student's advantage to acquire as many of these hours in the prepharmacy portion of the curriculum as possible.

[3]A minimum of 7 hours of pharmacy elective courses is required. The following courses are representative of the elective courses available.

- MDCM 692 Problems in Medicinal Chemistry
- PHCH 692 Clinical Pharmacokinetics
- PHCH 694 Problems in Pharmaceutical Chemistry
- P&TX 684 Advanced Topics in Drug Therapy
- PHPR 425 Pharmacy Practice for the Geriatric Patient
- PHPR 602 Controversies in Pharmacy Practice

[4]May be taken in fourth year spring semester or fifth year fall semester.

Pharmacists' Professional Services, Related to Traditional Drug Therapy Management

1. *Patient Assessment.* The pharmacist assesses the patient's health condition as it relates to drug therapy by reviewing routine vital signs (for example, an assessment of anti-hypertensive drug therapy by taking the patient's blood pressure).

2. *Patient Counseling.* After determining the most appropriate medication for the patient, the pharmacist counsels the patient on how to take medications, potential side effects, and dosage. In some cases, extended patient counseling is necessary due to the complexity of a patient's drug-related problem(s). The pharmacist gives patients personalized information about their ailments and the medications to make certain that they understand the drug regimen. The pharmacist also recommends certain changes in life-style and diet, if necessary, to hasten recovery from or prevent an illness.

3. *Patient Education and Training.* The pharmacist trains and educates the patient beyond counseling when the drug prescribed has complex usage instructions or complex administration (for example, extended education or training provided so patients appropriately use inhalers or drugs they must inject themselves).

   Patient education and training may also require pharmacists to offer patients written information on their specific drug regimens.

4. *Follow-up and Compliance Monitoring.* The pharmacist follows up with the patient, either by phoning or setting up an appointment, to ensure compliance with the drug therapy. Follow-up is necessary to ensure that patients comply with the drug regimen.

5. *Change of Dosage.* The pharmacist changes the drug dosage, form, or duration with prescriber authorization due to inappropriate or incorrect dose or dosage regimen prescribed.

6. *Discontinuation of Medication.* The pharmacist discontinues the patient's medication with prescriber authorization.

7. *Decision Not to Dispense.* The pharmacist does not dispense the medication after contact with and the authorization of the prescriber.

8. *Generic Product Selection.* The pharmacist dispenses a generic drug when the prescriber recommends a brand-name drug for which there is an appropriate generic equivalent.

9. *Therapeutic Interchange.* The pharmacist dispenses a therapeutically equivalent drug with prescriber authorization.

   The pharmacist-physician consultation that can lead to the physician's approval of an equally effective but less costly therapeutically equivalent medication should be part of a cost-effective outpatient pharmacy services benefit. Clear protocols and guidelines developed jointly by pharmacists and physicians must *responsibly* manage the use of drugs.

10. *Case Management.* The patient is referred to a pharmacist by a physician or a health plan for case management of a patient's drug therapy through a customized care program developed by the pharmacist, the physician, and/or the health plan.

    Patients with chronic illnesses—asthma, hypertension, and diabetes, among others—require thorough and ongoing monitoring of their conditions and drug therapy. For example, pharmacists perform blood glucose screening for diabetic patients. The medications used to treat such ailments, if used improperly by the patients, are more likely to cause severe health problems than medications used for treatment of most other conditions.

11. *Nonprescription Drug Therapy Interventions.* The pharmacist recommends a nonprescription medication for the patient based on symptoms and problems presented and counsels the patient on its proper use. The pharmacist can promote cost-effective, quality care by helping consumers choose appropriate nonprescription medications.

Core elements of the protocol should include the following:

a. A written statement specifying that prescriptive authority of the stated physician or physician group practice is delegated to the pharmacist(s).
b. The prescribing activities that are delegated must be clear to both the physician(s) and pharmacist(s).
c. The scope of practice for the pharmacist should be defined for each protocol.
d. Limits are identified beyond which the physician must be contacted in order for the pharmacist to proceed.
e. Procedures are clearly defined for documenting the pharmacist's practice decisions and care provided.
f. A time limit for each protocol arrangement should exist, beyond which the protocol should be reviewed and revised, if necessary.
g. A system should exist in which the physician and pharmacist periodically evaluate the quality of care provided to patients who are treated using the protocol treatment guidelines.
h. Pharmacists must demonstrate and maintain knowledge and competence needed to meet appropriate standards of practice.

h:new-sec.act

Testimony
HB 2216
House Health and Services Committee
February 9, 1995
Drug Selection Under Protocol

As health-care needs change, so we too, must change to meet these needs. Currently providing quality health-care to rural and under-served areas of Kansas is one such need. As you already know, physicians are always in demand in these areas. One way to provide primary health-care to such areas, would be the inclusion of pharmacists' participation in the primary care of patients under the supervision of qualified physicians. Pharmacists, traditionally have always worked closely with physicians to coordinate drug therapy for the benefit of their patients. Historically, pharmacists have had prescriptive authority, starting in Great Britain in the 1600's and carrying through to the early 1800's here in the United States. Many pharmacists today, in a number of states (New Mexico, Nevada, California, South Dakota, Mississippi, Missouri and Oregon) have statutory authority for the management of patients under protocol.

In the past, the need for such authority was to fill a void, and today the purpose once again, is in response to a need. Many under-served and rural areas of Kansas today lack a physician or will have a physician retire in the near future. These same areas also face the likelihood of loosing their pharmacists due to current market trends and retirement. By authorizing pharmacists to work under protocol with a physician, we can better utilize existing manpower to fulfill the heath-care needs of these areas.

Additionally, such measures allow the provision of specialized services in areas currently lacking such. The outreach clinic that Dr. Strickland and I initiated, addressed just such a void in the case of asthma and allergy. In this situation, there were no physicians specializing in allergy or asthma where I live, yet we had a large number of people that were suffering from these conditions. A protocol was developed (see attached), and guidelines were established for an asthma and allergy clinic. After one year of operation, we have treated about 40 to 50 people, who either had no way of obtaining comparable services (due to physical or geographical constraints) or who had no idea of the origin of their suffering, and as such, did not know to whom to turn. Many areas in which clinics could be set up under protocol exist: diabetes, smoking cessation, anti-coagulation, nutrition, hypertension, hypercholesterol and immunizations to name just a few.

In such clinics, the physician is responsible for the initial work-up and diagnosis. In the clinic we are operating, my training in pharmacotherapy allows me to start the medication regimen and adjust it according to individual responses, under protocol. In order to modify treatment plans, laboratory and minor physical assessment must be done. By allowing, under protocol, the ordering of laboratory tests and limited physical assessment (ie. pulmonary function testing) I can assess how the patient is responding to the medication and make adjustments accordingly. If problems are encountered or questions arise, the physician is a phone call away, and all lab and assessment values can be faxed to him immediately. All documentation is either faxed or sent to his office as patients' therapies are modified. Patient response to these clinics have been well received, with

many commenting on how well their therapies are working and how much their quality of life has been improved.

All of our patients have benefited from our clinics and at this point in time, at least three other physicians outside Stafford County have expressed interest in setting up clinics under protocol to provide specialized care to those patients who need it. By no means would such authority take anything away from either the patient or physician. It will however, provide them the opportunity to individualize patient therapy, provide positive patient outcomes and, in many cases, reduce the cost of medication treatment to the patient.

Providing statutory authority to allow pharmacists to manage patients under drug therapy protocols will address a major concern of both pharmacists and physicians alike. Our protocol and arrangement falls under the "Captain of the Ship Doctrine." The possibility exists that some physicians and pharmacists will be reluctant to enter into protocol arrangements because the Kansas Pharmacy Practice Act is silent on the issue of practicing under protocols. Furthermore, as a practicing pharmacist, I would feel more comfortable from a liability standpoint, if I had the Kansas Pharmacy Practice Act behind me. Additionally, such statutory authority will be helpful in showing third party providers that pharmacists have a direct impact on patient care and can in may instances provide a cost saving service.

For health-care in Kansas to move forward and meet the needs of its citizens, we must be progressive and fulfill these needs. One way to help fulfill this immediate need of rural and under-served areas in Kansas, is to authorize pharmacists to provide primary health care, under the supervision of qualified physicians. Such statutory authority would serve to address the legal and liability concerns of physicians and pharmacists, as well as enhance services available. With physician support, such as that which I have from Dr. Strickland (see attached letter), I see no reason why Kansas cannot be a leader in providing quality health-care for its citizens.

Robert D. Haneke, R.Ph.,PharmD,BCPS
102 N. Main
Stafford, Kansas 67578
316-234-5214

Physician Authorization

I authorize Robert D. Haneke, PharmD., to practice in accordance with the following procedures for any patient under my care.

1. Initiate drug therapy within the following therapeutic categories:

   >Antibiotics*
   >Anti-diabetics
   >Antihistamines
   >Anti-hypertensives
   >Antitussives/expectorants*
   >B-agonists, anticholinergics, steroids, anti-inflammatories for asthma/COPD, allergies, etc. (oral, inhalation, IM, IV)
   >Eye products (artificial tears, lubricants, decongestants, antihistamines, anti-inflammatories)
   >Inhalation assist devices
   >Lipid modifing products
   >Mouth and throat products (lozenges, troches, sprays)
   >Nasal products (decongestants, antihistamines, anti-inflammatories)
   >Substitution within a therapeutic class
   >Vitamins, minerals, hematinics, electrolytes
   *Short-term, acute use only--not to exceed 14 days.

2. Adjust the frequency of administration, dosage form, or dosage of a drug or drugs ordered by the prescriber.

3. Initiate or perform routine patient assessment procedures incidental to drug therapy, including, but not limited to blood pressure, pulse, respiration, temperature, weight, audiometry, tympanometry, allergy skin testing, pulmonary function tests and peak expiratory flow measurements.

4. Order drug therapy related laboratory tests and screening tests.

5. Administer drugs or biologicals pursuant to a prescriber's order.

M.H.V. Strickland, M.D. ,MD
M.H.V. Strickland, MD

Robert D. Haneke PharmD
Robert D. Haneke, Pharm.D.

Date 12/8/94

Procedural Restrictions: √ As indicated below
__None

Copy of visits should be mailed or faxed to main office if patients are seen on days when I am not in the Stafford Location.

6 - 3

M.H.V. STRICKLAND, M.D.

DIPLOMATE, AMERICAN BOARD OF ALLERGY/IMMUNOLOGY
ADULT AND PEDIATRIC ALLERGY
710 NORTH WOODCHUCK
WICHITA, KANSAS 67212
(316) 722-4800

February 6, 1995

To Whom it May Concern;

I am writing a position statement concerning protocols between physicians and pharmacists (pharmacotherapists).

It is my impression that a closer relationship between the physician and pharmacist or pharmacotherapist will result in higher quality of primary care being delivered to patients. The pharmacist can assume responsibility in their area of expertise, which will free the physician to spend time on other areas of importance such as physical examination and effective communication with the patient.

The cooperation of physician and pharmacist draws together the knowledge and expertise of the two healthcare professionals who understand the most about medications.

The use of pharmacists and pharmacotherapists as a part of the patient care team allows for higher standards of care to be extended to rural and under-served areas of Kansas.

It is possible for physicians and pharmacists or pharmacotherapists, working under protocols an extended range of speciality service in rural areas where these services are not now available.

I have had the pleasure of working with Dr. Robert Haneke for over one year now in my primary office in Wichita and a satellite clinic in Stafford, Kansas. He is highly knowledgeable and highly competent in the Pharmacotherapeutic basis of medical practice. He is highly competent in his ability to initiate, modify, and assess drug therapy. He, is as well, highly competent to follow-up chronic drug therapy. Dr. Haneke has shown a high level of proficiency in assessing physical and laboratory parameters that relate to evaluating patients responses to drug therapy.

I have utitlized Dr. Haneke to help with my most difficult cases, those patients with serious medical therapy requiring multiple drugs that often have siginificant side effects and drug-drug interactions. He has been extremely valuable in assessing patients pharmacotherapy needs and evaluating their medication outcomes. He has been very useful in initiating and modifying treatment dependent on patients responses to therapy.

6 - 4

I feel that Dr. Haneke has been of great help to many patients. Improved outcomes have occurred in response to his assessment, initiation and modification of treatment. I am interested in studying outcomes utilizing Dr. Haneke. Not only should beneficial response to therapy be considered, but ease of therapy (i.e. one capsule a day versus four) and economy of therapy (low cost with good outcome versus high cost with good outcome).

Outcomes have been evaluated by chart reviews, telephone consultation or conversation, and faxed records (lab, pulmonary function tests, etc.). I think that enhanced communications, and written protocols between physicians and pharmacists can result in superior outcomes, greater economy and greater patient satisfaction.

I support the implementation of legislation that will allow pharmacists with skills such as displayed by Dr. Haneke to work under protocol with a sponsoring physician.

With the average patient taking six drugs, the time has arrived for greater cooperation between physicians and pharmacotherapists and pharmacists.

At many medical centers, the pharmacist or pharmacotherapist is an integral part of the patient care team and makes hospital rounds with the doctors, physician assistants, and nurses. I feel the need to extend this approach to outpatients as well.

Sincerely,

M.H.V. Strickland, M.D.

M.H.V. Strickland, M.D., F.A.A.A.I., F.A.C.A.I., F.A.A.P., A.C.P.

TESTIMONY

Stephen L. Smith, R.Ph.
Steve's Corner Drug
Hiawatha, KS

Background info:

BS in Pharmacy from Kansas University
Two years Army hospital pharmacy
Twenty-five years owner operator of Steve's Corner Drug
Seventeen years as pharmacy consultant to nursing homes (five)

Questions:

Can a pharmacist participating in the management of a patient's drug therapy under written protocol by a physician be beneficial to the outcome of patient, physician, and health care dollars?

Can a pharmacist work in this new environment without disturbing the balance between, physician, patient and pharmacist?

How do I as a rural pharmacist envision the protocol procedure in my setting?

Will protocol vary from pharmacist to physician?

Answers:

I will now address several areas in a pharmacy setting that should answer the above questions and show how a physician-pharmacist protocol will be a plus-plus for patient, physician, pharmacist, and overall healthcare dollars and better patient outcomes.

Area I. Medication Use Management--Drug Disease State Monitoring.

Under protocol, the physician would make the diagnosis and pass the information to the pharmacist and states therapeutic class of drug requested and starting dose. The pharmacist selects the drug if there is more than one choice, based on several criteria such as: patient's previous compliance, side effect profile, and compatibility with the patient's drug regimen. Once medication is selected the

pharmacist then sets up the follow-up phone calls and visits to assess how the patient is responding to the medication. According to the assessment the dose of the medication could be lowered or raised or medication could be stopped, and the physician would be kept informed either by phone or fax from start to finish. How does this save dollars? Say for instance a person is started on a hypertensive med -- how many times does the patient have to revisit the physician office before correct med and dose is achieved? The above procedure will save these visits. How many times does a person not continue their meds due to side effects and become noncompliant? In relation to hypertensive meds this can be as high as fifty percent of the time. This will create more dollars when the patient goes to the hospital. The pharmacist-physician protocol will create a much higher rate of compliance.

Area II. Late evening and weekend situations.

Since pharmacists are the most assessable healthcare provider, it is not unusual for people to come to the pharmacist in late evening or weekends with an ailment. The way the system works today the pharmacist, if physician can't be found, has to refer the person to an emergency room of a hospital. This is costly two ways. First when the person goes to the emergency and second if they choose not to go and forty-eight hours later have to be hospitalized on Monday morning. Under the physician-pharmacist protocol a pharmacist, if he has written protocol and the disease state is a part of the protocol, after assessing the situation may adjust/modify medication therapy. Example: adult diabetic patient comes into pharmacy on weekend and physician is unavailable. Their blood sugar is above 240. Under protocol, the pharmacist could adjust the patient's medication dosage and fax intervention information to the physician for Monday morning. This would save an

Emergency Room visit. This weekend and evening is a big dollar item with healthcare.

Area III. Nursing Home Psychotropic Medications.

All nursing homes have to address residents and their mind altering drugs on a regular basis. Being a nursing home consultant this area of psychotropic medications takes a great deal of nursing and pharmacist time, sometimes daily, to best help residents for a better lifestyle. With physician-pharmacist protocol the pharmacist could assess the dose changes up or down on a when needed basis to that the nurse and pharmacist wouldn't have to call the physician daily, weekly, or monthly.

Area IV. OTC Medications.

There are many OTC meds, and the list keeps growing, that can lead to medication problems and interactions. Quite often the patient doesn't relate their use of OTC meds to their physician. With the physician-pharmacist protocol a lot more channels of shared information will happen that can be very helpful to the patient.

Area V. Physician Time.

By creating the physician-pharmacist protocol it will help free up time for the physician as some of the follow up and compliance issues will be lifted from the physician and given to the pharmacist. It will prevent many people from falling through the cracks that eventually will lead to more health care dollars.

g:\kpha]smith.tst

KANSAS MEDICAL SOCIETY
623 SW 10th Ave. • Topeka, Kansas 66612 • (913) 235-2383
WATS 800-332-0156 FAX 913-235-5114

February 9, 1995

TO: House Health and Human Services Committee

FROM: Jerry Slaughter
Executive Director

SUBJECT: HB 2216; concerning prescribing by pharmacists

The Kansas Medical Society appreciates the opportunity to appear today as you consider HB 2216, which would allow pharmacists to prescribe drugs under written protocols.

As we pointed out when you heard the bill which would have granted independent prescribing authority to ARNPs, we have the utmost respect for pharmacists and their unique contribution to the health care team. Just as nurses are essential to the system, so too are pharmacists. Many physicians across the state work closely with community pharmacists in a collaborative and consultative arrangement that can be extremely flexible under current law.

Unfortunately, we cannot support this bill. HB 2216 represents a significant expansion of the scope of practice for pharmacists, and we have trouble understanding the need for the change. Current law allows physicians to delegate acts which constitute the practice of medicine to persons who work under their guidance or supervision. It is our belief that unique practice arrangements can be worked out under existing law which can accommodate what pharmacists claim they seek.

We have some experience in this area from which we can draw parallels. Several years ago the advanced registered nurse practitioners asked the legislature to grant them the ability to prescribe under protocols within the context of a collaborative, physician-directed health care team. We supported their request, because they stated emphatically that they had no intention of prescribing or practicing independently. We just heard last week that they now want to *compete* with physicians, and they must have independent prescribing authority to do so. ARNPs were not trained, nor intended, to be physician substitutes. They were meant to provide greater access to *physician-directed* services, supplemented by the unique capabilities which advanced trained nurses possess.

Are we about to enter into the same sort of arrangement with pharmacists? Unquestionably, they have extensive knowledge about pharmaceuticals, but does that automatically translate into the ability to clinically evaluate and treat patients? What sort of clinical preparation do they have? How does it compare with that of physicians, whose services they now seek to provide under protocols? Is there really a need for this legislation: are people not receiving proper drug therapy when they need it?

There is a temptation to look at the practice of medicine as merely a collection of separate and distinct skills, any one of which can be easily learned, or delegated, to a substitute with less complete training who can then do the same thing physicians do.. However, it is a mistake to view the practice of medicine in that way. The reason that medical education is so comprehensive is that there is simply no substitute for a broad, thorough and rigorous educational experience to prepare one for the responsibility of delivering the full spectrum of patient care. An in depth knowledge of pharmacology is good, but in itself does not qualify someone to, in essence, practice medicine.

There is another point in all this. You have heard from health providers this year who are seeking to expand their scope of practice through legislation. All have one thing in common: they want to provide services which heretofore by law required a medical education. One has to wonder why those who really want to practice medicine just don't go to medical school. Were they confused about the role of the profession they entered? Surely they had some knowledge of the legal parameters that would define their scope of practice upon graduation. There is simply no shortcut to preparing for any aspect of the practice of medicine, including the prescribing of drugs.

Finally, based on testimony presented last week on the ARNP bill, serious questions must be asked about the use of protocols in these situations. The nurses testified that the system was routinely "gamed" and that the law amounted to nothing more than "fraud" and a "sham." If that is what has become of a fairly simple and well-intended concept, then it might be time to reevaluate the whole idea. The use of protocols was a *quality assurance* mechanism, not just a hollow exercise in paperwork. At the very least, it should make one question whether some additional safeguards should be built in before other similar arrangements are authorized.

In summary, we have the greatest respect for pharmacists. Even though we cannot support HB 2216 in its present form, we are willing to discuss the issue and look for common ground. One option the committee might want to consider is sending this bill to an interim committee for additional study. Thank you for considering our comments.

Kansas Association of Osteopathic Medicine

Harold E. Riehm, Executive Director

1260 S.W. Topeka Blvd.
Topeka, Kansas 66612
(913) 234-5563
(913) 234-5564 Fax

February 9, 1995

To: Chairman Mayans and Members, Senate Committee on Health and Human Resources

From: Harold E. Riehm, Executive Director, KAOM

Subject: Testimony on H.B. 2216

Thank you for this opportunity to present our views on H.B. 2216. We appear today in opposition to this Bill.

Consistent with testimony we have presented on other legislative matters dealing with prescribing authority, we emphasize both the critical importance of drug therapy to quality patient health care, and the importance of drug therapy being the prerogative of a person familiar with a patient's overall health care, i.e., the patient's physician.

Pharmacists are important players in the health care equation. Their advice and consultation is a great service to both physicians and the patients for whom they care. However, in our examination of this Bill and how it would operate, we see little to be gained in service to the patient and some possible problems in the continuity and coordination of patient care.

Specifically, our concerns are these. I will be pleased to elaborate on any of these as Committee members may wish.

a. While H.B. 2216 may appear to enhance cooperation between a physician and pharmacist, it is just as likely to deemphasize a cooperative approach by encouraging a pharmacist to act independent of a physician in a way dysfunctional to a team approach.

b. Were this Bill to provide that every change in formulary provisions, dosage, etc. made by a pharmacist had to be reported to the prescribing physician it would be more palatable--but then we would be right back to the normal pattern that characterizes consultation among pharmacists and physicians when questions arise as to the adequacy or choice of therapy.

c. We are concerned that the physician may not always be fully aware of changes made by a pharmacist, under protocol arrangements. it is imperative, we think, that subsequent patient care leave little room for confusion about what changes were made and when.

d. Most physicians indicate that many changes in a prescription can be initiated by a phone call, either by a patient to a physician or by a pharmacist to a physician after the pharmacist has heard a patient's concerns.

e. There are several logistical problems that the Bill does not address, such as:

    1. Who dictates protocol content? The Board of Pharmacy, Board of Healing Arts, etc.? Is there to be a model protocol agreement described by rule and reg?

2. Is there a limit to the number of pharmacists with which a physician may enter into protocol agreements?

3. Are there restraint of trade implications of a physician "steering" patients to a particular pharmacist because of the existence of protocol?

4. How does the physician designate which prescriptions he wishes to be subject to protocol arrangements?

f. Lastly, there are dramatic changes underway in the provision of health care. Frequent reference is made to managed care emphasizing less time spent on patient care. I will not presume to even suggest to you that physicians might be encouraged or tempted to put in place a protocol because it "saves time" in his or her treatment of the patient by transferring drug therapy prerogatives to a pharmacist. But neither do we want to be a party to anything that even alludes to this.

In conclusion, we think patients are best served by the system the way it functions today. We think present opportunities for physician-pharmacist communication are widely used and sufficient to permit needed flexibility.

I will be pleased to respond to any questions you may have.

KANSAS BOARD OF HEALING ARTS

BILL GRAVES
Governor

LAWRENCE T. BUENING, JR.
Executive Director

235 S. Topeka Blvd.
Topeka, KS 66603-3068
(913) 296-7413
FAX # (913) 296-0852

M E M O R A N D U M

TO: The House Committee on Health and Human Services

FROM: Lawrence T. Buening, Jr.
Executive Director

DATE: February 9, 1995

RE: **HOUSE BILL NO. 2216**

Thank you for the opportunity to appear before you and provide information regarding House Bill No. 2216. As the Board's Legislative Committee met on January 20 and the Board as a whole will meet on February 11, the Board has not had an opportunity to take a formal position on this bill. However, the Board has taken some generic positions on issues presented by this bill.

K.S.A. 65-2872(g) states that individuals are not to be construed to be engaged in the practice of the healing arts if their professional services "are performed under the supervision or by order of or by referral from a practitioner who is licensed under this act". This has been referred to as the captain of the ship doctrine. Therefore, it is the Board's position that the Legislature has previously authorized physicians to delegate functions such as the management of drug therapy to other individuals.

The situation where the Healing Arts Act will allow delegation of certain functions to persons licensed under other acts, but whose acts prevent the performance of those functions is not unusual. For instance, K.S.A. 65-2896e allows physicians' assistants to perform acts which constitute the practice of medicine and surgery to the extent and in the manner authorized by the responsible physician. This would include the ordering of physical therapy. However, under the Physical Therapy Laws, a physical therapist, under K.S.A. 65-2901, may initiate treatment only after consultation with and approval by a physician licensed to practice medicine and surgery, a licensed podiatrist or a

licensed dentist. Similarly, chiropractors may delegate physical therapy to a physical therapist under the Healing Arts Act. However, the same statute above referred to prohibits the physical therapist from initiating treatment based upon an order from a chiropractor.

If the Legislature feels it is appropriate to specify by statute that pharmacists may participate in the management of a patient's drug therapy, the Board would suggest that the language contained in K.S.A. 65-2896e(b) and K.S.A. 65-1130(d) relating to the transmittal of prescription orders by physicians' assistants and advanced registered nurse practitioners be considered.

In conclusion, the Board has consistently been of the opinion that if the Legislature by statute wishes to authorize individuals to engage in the practice of medicine and surgery, that statutory language should provide such authorization be under the auspices of the State Board of Healing Arts which is the entity that licenses individuals to practice medicine and surgery.

Thank you for the opportunity to appear in front of you. I would be happy to respond to any questions.