

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman Jim Barnett at 1:30 P.M. on February 20, 2008 in Room 136-N of the Capitol.

All members were present.

Committee staff present:

Emalene Correll, Kansas Legislative Research Department
Terri Weber, Kansas Legislative Research Department
Sara Zafar, Kansas Legislative Research Department
Nobuko Folmsbee, Revisor of Statutes
Renae Jefferies, Revisor of Statutes
Jan Lunn, Committee Secretary

Conferees appearing before the committee:

Frank Whitchurch, RPh, Manager Prescription Solutions, Overland Park, KS, and Member of the Kansas Board of Pharmacy
Debra Billingsley, Kansas State Board of Pharmacy
Mike Larkin, Executive Director, Kansas Pharmacists Association
Julie Hein, Kansas Pharmacy Coalition
William W. Sneed, Legislative Counsel, Express Scripts
Steven Borel, Attorney-at Law, Kansas Association for Justice
Mark W. Stafford, General Counsel, Kansas Board of Healing Arts
Jerry Slaughter, Kansas Medical Society

Others attending:

See attached list.

SB 549 - Pharmacy Continuous Quality Improvement (CQI) Programs and Non-resident Pharmacy Regulations

Senator Barnett opened the meeting recognizing Nobuko Folmsbee who briefed those attending on **SB 549**. The proposed legislation creates a continuous quality improvement program in each pharmacy for the purpose of identifying, recording, and developing action plans to address errors that occur in dispensing prescription medications. Records generated by such programs are confidential and privileged peer review documents, and, thus, not subject to discovery, subpoena, or other legal compulsion. The Board of Pharmacy would provide oversight of the CQI Program. The bill also amends regulations on non-resident pharmacies in Kansas under KSA 65-1657, to include a designated "pharmacist-in-charge" (PIC) licensed in the State of Kansas through the Board of Pharmacy, and without a designated PIC, the non-resident pharmacy could only operate in the State of Kansas thirty (30) days. (Attachment 1)

Frank Whitchurch, RPh and member of the Kansas Board of Pharmacy spoke in support of **SB 549**. He outlined the proposed program would create a proactive approach focused on reducing errors, on routine review of processes, and on analyses of root causes involved in documented errors. Mr. Whitchurch mentioned sixteen (16) other states have similar programs, and with the burgeoning internet prescription-drug markets and out-of-state mail order pharmacies, it is believed this program can improve quality and safety for consumers. (Attachment 2)

Chairman Barnett recognized Debra Billingsley, Executive Secretary, Kansas Board of Pharmacy. Ms. Billingsley added that the proposed legislation provides to pharmacists the same peer review protection as is provided to other medical providers. (Attachment 3)

Mike Larkin, representing the Kansas Pharmacists Association, spoke in favor of **SB 549**. He added that his group requested an amendment that would implement a CQI program on July 1, 2009, (instead of January 1, 2009) to provide adequate time for education to pharmacists (Attachment 4). This attachment, therefore, becomes part of this record.

Julie Hein, representing the Kansas Pharmacy Coalition and the Kansas Association of Chain Drug Stores, spoke as a proponent of **SB 549**. However, Ms. Hein suggested that language mirroring KSA 650-4915 c) be added which specifies that any CQI reports, conclusions, records, or discussions be done only in closed sessions, and that pharmacists and pharmacy personnel participating in CQI programs are afforded the same protection as other peer review processes. Ms. Hein's testimony is attached, and therefore, is incorporated into this record. (Attachment 5)

Mr. William W. Sneed, Legislative Counsel, Express Scripts was recognized by Chairman Barnett. Mr.

CONTINUATION SHEET

MINUTES OF THE Senate Public Health and Welfare Committee at 1:30 P.M. on February 20, 2008 in Room 136-N of the Capitol.

Sneed spoke in opposition to **SB 549** in its current form. He suggested an amendment that would establish financial penalties on non-resident pharmacies when the Kansas Board of Pharmacy issues an inquiry to a non-resident pharmacy and the non-resident pharmacy does not respond. This amendment would eliminate the non-resident pharmacy requirement for a pharmacist-in-charge (PIC) licensed in the State of Kansas through the Board of Pharmacy. Mr. Sneed's testimony is attached and made part of these minutes. (Attachment 6)

Mr. Steven J. Borel, Attorney at Law, Kansas Association for Justice, spoke in opposition to **SB 549** citing the Supreme Court Decision of Adams v. St. Francis Medical Center which held that citizens have a constitutional right to factual information related to their case and such information cannot be shielded by the peer review process. Mr. Borel suggested an amendment to clarify that the Supreme Court's decision applies to pharmacy CQI programs. Mr. Borel's testimony is attached, and therefore, becomes part of this record (Attachment 7). In addition, Mr. Borel discussed his concerns related to the minutes of the "Continuous Quality Improvement Task Force" of the Kansas Pharmacists Association which suggested revocation of the incident reporting regulation (Attachment 8).

Questions were asked by Senators Palmer, Wagle, and Brungardt relating to prescriptions dispensed by internet providers and those from outside the United States, pharmacy license reciprocity, and accountability for protecting Kansas citizens. Chairman Barnett indicated that in the interest of time and since **SB 596** was also on the agenda, further discussion on **SB 549** would be heard on Thursday, February 21, 2008.

SB 596 - Board of healing arts; cosmetic or aesthetic purpose included in the practice

Mark Stafford, General Counsel, Kansas State Board of Healing Arts, spoke in support of **SB 596**, that was initially introduced by the Board of Healing Arts. The bill was introduced to eliminate procedures and services that are aesthetic or cosmetic in nature being performed by persons who are not licensed to practice medicine or surgery. Mr. Stafford's testimony is attached and incorporated into this record (Attachment 9).

Jerry Slaughter, Executive Director of the Kansas Medical Society, distributed testimony (Attachment 10) offering an additional amendment defining surgery, and he indicated his support of **SB 596**. A copy of the balloon amendment was distributed to those attending the meeting (Attachment 11).

Chairman Barnett indicated continued discussion and possible final action will be heard on Thursday, February 21, 2008.

Minutes of the February 13 and 14, 2008, meetings were distributed and reviewed by Committee members. Senator Haley moved to accept the minutes as submitted; Senator Schmidt seconded the motion. The motion passed.

Senator Barnett adjourned the meeting at 2:35pm.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE GUEST LIST

DATE: February 20, 2008

NAME	REPRESENTING
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FEB 20, 2008

Jay Sawyer

KAS

Dan Morin

KMS

Bob Williams Ks. Assoc. Osteopathic Medicine

Bill Sneed

Express Scripts

Jessica Rojas

student

Todd Fleischer

Kansas Optometric Association

MIKE LARKIN

KANSAS PHARMACISTS ASSOCIATION

Julie Kern

KPC

Oliver Delsky

BOP

Frank W. Schneider

KBOP

Delva Billingsley

KBOP

Richard Sammons

Kenney Assoc

Gabrielle Huckaby

Sen. Dennis Pyle

Steven Borel

KAS

Callie Hattle

Ks Assn of Justice

Office of Revisor of Statutes

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MEMORANDUM

To: Senate Committee on Public Health and Welfare
From: Nobuko K. Folmsbee, Assistant Revisor
Date: February 20, 2008
Subject: SB 549, Pharmacy Continuous Quality Improvement (CQI) Programs and Nonresident Pharmacy Regulations

SB 549 deals with two issues regarding the pharmacy act. First, it creates a continuous quality improvement (CQI) program in each pharmacy. This program aims to identify and record errors that occur in dispensing or furnishing prescription medications so that those errors would not happen again. The records generated as part of the pharmacy CQI program are confidential and privileged peer review documents and not subject to discovery, subpoena or other legal compulsion. No one who attended the meetings as part of the CQI program shall be compelled to testify in any civil, criminal or administrative action. However, the board of pharmacy may obtain the record and call witnesses to testify in its administrative proceedings. Further, patients may access their own prescription records. The board of pharmacy may adopt rules and regulations in establishing the functions and record keeping of a pharmacy CQI program.

Second, this bill amends the regulations on nonresident pharmacy in K.S.A. 65-1657. This statute covers the nonresident pharmacy registration requirements, required information, drug product selection rules, interstate delivery guidelines, disciplinary action, prohibited advertising unless registered, penalties for violations and injunctive relief. Any nonresident pharmacy must register under the statute in order to ship, mail or

deliver prescription medications to a patient in this state. This bill requires the nonresident pharmacy to designate a pharmacist in charge who has a license from the board of pharmacy. Without the pharmacist in charge, nonresident pharmacy cannot operate more than 30 days. Designated pharmacist in charge must obtain the minimum passing score on the pharmacist-in-charge examination and agree to notify the board in writing within 5 days of ceasing to serve as the pharmacist in charge of the nonresident pharmacy. The notice shall include the name of the pharmacist, the name and address of the nonresident pharmacy and the date the pharmacist in charge ceased to serve.

Testimony in Support
Of
SENATE BILL No 549
Presented by Frank Whitchurch, RPh
Member of the Kansas Board of Pharmacy
And
Manager of Pharmacy Operations
Prescription Solutions
Overland Park Kansas

Chairman Barnett,
Members of the Senate Health and Welfare Committee:

I wish to begin by expressing my thanks to Chairman Barnett and members of the committee for allowing me the opportunity to speak in support of this legislation. My testimony will provide the committee with useful information concerning this bill, its genesis and more importantly why we at the board of pharmacy consider this legislation to be the one of the most important bills affecting public health in years

My name is Frank Whitchurch. I am a licensed Kansas pharmacist with over 30 years of practice experience. I am currently serving my second term on the board of pharmacy.

My current practice setting is as Manager of Pharmacy Operations and Pharmacist in Charge at Prescription Solutions in Overland Park Kansas. Prescription Solutions is the division of United Health Care. Our company is the Mail Services division of United Health Care.

Senate Bill 549, introduced by Senator Schmidt, addresses two areas of great concern to the board and implementation of this bill will dramatically and positively impact public health.

Section 1 will improve the health of all Kansans by providing for the implementation of a Continuous Quality Improvement program which will lead to a reduction in errors in all pharmacies in our state.

Section 2 will allow the people of Kansas, acting through their board of pharmacy, to demand a higher level of accountability from non resident pharmacies by modifying currently existing statute to require all non resident pharmacies that ship prescription drugs to Kansas patients to designate a pharmacist in charge who will hold a license in our state. This change then requires all non resident pharmacies to have the same accountability structure as in state pharmacies.

The question that needs to be asked of and answered by the board is if this legislation is necessary.

The answer is emphatically YES. Enactment of this bill is absolutely necessary in today's pharmacy practice environment which involves high volume dispensing of very potent medications

Please allow me to comment further.

One of the characteristics of highly successful organizations is the ability to not only be reactive but proactive as it seeks to successfully complete its mission.

I am very happy to report to you that this Board is not only concerned with reacting to errors but wants to actively take steps to prevent them. We have reviewed the best of the latest thinking on prevention of errors and incorporated it in the form of Senate Bill 549. This bill reflects the cutting edge of error prevention.

Implementation of a Continuous Quality Improvement program in our pharmacies will reduce errors by mandating that each practice setting review its dispensing process on a regular basis, seek to determine the root cause of all errors and make process changes to avoid a repetition of the error. It will greatly encourage the reporting of all errors great and small discovered internally or reported by a patient. Honest reporting of all errors is key to process improvement with root cause analysis and reconciliation as the final step. It is only possible in a non punitive environment with deliberations centered around process improvement protected from discovery or other legal processes.

Current statute and regulation does not allow this type of process improvement nor does it mandate the regular process review meetings. This legislation will allow the needed improvements

When we implement this statute we will be joining with 16 other states and counting that are mandating a CQI program. We will be counted among those that want the highest level of patient protection, that understand that great strides in patient safety can be made with minimal cost, and be numbered among those willing to that take the extra step to protect our citizens

The second provision of this bill asks for a minor change in a current statute to enhance the ability of the board to regulate non resident pharmacies. It asks that non residents designate just one of their pharmacist staff to hold a Kansas License and take overall responsibility for ensuring that they operate their out of state pharmacy at the same level of excellence required for pharmacies operating within Kansas as reflected in the rest of the statute.

When the current statute was enacted in the early 1990's more than a decade ago, the vast majority of our citizens prescriptions were filled at in state pharmacies, internet pharmacies and dispensing of prescriptions from out of state providers was minimal. The level of scrutiny the board required was minimal as well.

Fast forward to 2008 with the board looking at an entirely different scenario then it faced years ago. The growth of internet pharmacies and out of state dispensers has been and continues to be explosive. Out of state dispensing into our state has grown exponentially. You will soon here testimony from our executive secretary as to numbers of dispensers, internet pharmacies and problems the board has had in trying to investigate and resolve our citizens complaints under existing statute

Currently there are 46 states that require non resident pharmacies to obtain a permit as a prerequisite to dispensing. Of these states 20% or 9 require the non resident pharmacy to have one of their pharmacists licensed in their state.

Recently I spoke with John Kirtley, assistant director of the Arkansas Board of Pharmacy, one of the states that require an out of state pharmacy have an Arkansas licensed pharmacist for non resident licensing.

We discussed why Arkansas took the step our board is proposing. In brief his remarks indicated that with the a Pharmacist in Charge licensed in the state citizens had a much higher level of assurance that their scripts were filled in accordance with the same standards required of in state pharmacies, that should a quality related event (complaint or error) occur, the board could expect 100% response rate to communications and to process changes the error would suggest be implemented. Prior to this requirement it was very difficult to effect change and gather data as no one person was taking responsibility for the operation of the pharmacy. The cost to the out of state entities is minimal compared to the benefits to the citizens of the state

Please help your Board of Pharmacy improve the service it provides our citizens. I now stand ready to answer any questions the committee may have on this matter



KANSAS BOARD OF PHARMACY
DEBRA BILLINGSLEY, EXECUTIVE DIRECTOR

KATHLEEN SEBELIUS, GOVERNOR

**Testimony concerning SB 549: Continuous Quality Improvement
Senate Public Health and Welfare
Presented by Debra Billingsley
On behalf of
The Kansas State Board of Pharmacy
February 20, 2008**

Senator Barnett, Members of the Committee:

My name is Debra Billingsley, and I am the Executive Secretary for the Kansas State Board of Pharmacy. Our Board is created by statute and is comprised of six members, each of whom is appointed by the Governor. Of the six, five are licensed pharmacists and one is a member of the general public. They are charged with protecting the health, safety and welfare of the citizens of Kansas and to educate and promote an understanding of pharmacy practices in Kansas.

The Board of Pharmacy supports SB 549 as a proactive measure to guard against errors that occur in pharmacy. Pharmacies have spent billions of dollars on safety technology and other improvements but as long as there is a human factor involved in filling prescriptions there are going to be errors. The National Association of Boards of Pharmacy recommended last year, through a resolution supported by all 50 states, that each state Board implement quality improvement programs.

Traditionally Board's have been reactive to errors and impose sanctions after an error has been made and a complaint received. Continuous quality assurance (CQI) is a non-punitive approach that redefines accountability and directs it in a productive and useful manner. New factors are constantly introduced in the pharmacy practice system and there will always be room for improvement. We are trying to reach out to the pharmacies by providing them with standards and procedures that will help improve their performance. This bill institutes a quarterly review of incidents in a pharmacy. The pharmacy will look at each error and analyze how the problem occurred and what can be done in the future to correct the problem. They would then use the findings to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent errors.

The pharmacy would be required to keep records of its CQI program on the pharmacy premises. Once a meeting has been held the pharmacy must create a summarization document that contains an analysis of remedial measures that are undertaken following the event. The purpose of the document is not to learn who is at fault or who is to blame. The focus is on what is being done in the future to correct the problems.

PUBLIC HEALTH AND WELFARE
DATE:
ATTACHMENT:

02/20/08

3

The Board would through its annual inspection process track how the pharmacy has formalized their CQI team. The pharmacy would be required to publicize changes to their pharmacy staff based on the CQI meetings. The pharmacy should improve their policies and procedures continually based on what they have learned through reviewing quality related events.

There are sixteen states that have taken these steps to ensure additional safety in the dispensing of prescription drugs. The Board of Pharmacy recommends this evaluation opportunity for measuring pharmacy performance in a positive manner. This is merely a peer review process and as such should be protected from discovery as are other peer review processes. The Board of Pharmacy opposes the recommendations made by the Kansas Association of Justice. The attorneys are currently able to obtain factual information related to errors and this bill would not affect that ability. The Board is asking that each pharmacy be required to study their errors and this information should not be discoverable.

The second portion of the bill relates to the requirement that a non-resident pharmacy licensed in Kansas have their pharmacist-in-charge (PIC) licensed as a pharmacist in Kansas. There are nine states that currently require the PIC to be licensed in every state they ship drugs to. The Board views this as a compliance issue so that pharmacies shipping into Kansas know and understand Kansas law. Currently, a non-resident pharmacy is required to provide the name of a responsible person who is responsible for receiving communications from the Board. The Kansas regulation requires the pharmacist to timely respond to any lawful request of the Board. The Board believes that by requiring the responsible pharmacist to be licensed in Kansas he will have a motivation to respond in a timely manner to the Board. The Board often finds that the number given on the application is for Customer Service and the individual's who answer the phone do not even know who the State Board of Pharmacy is. The Board has had instances in which we were unable to obtain a response from either the licensee or the State Board of Pharmacy where the non-resident pharmacy was located. If an individual is personally licensed in Kansas and their response or lack thereof is tied to their license we believe we would not have the compliance issues that we currently have. We have drugs shipped in to the state that do not follow the non-resident pharmacy statutes and regulations and the PIC should have a better understanding of Kansas law. The Board staff has had discussions with some of the companies that this change would affect. The Board would not be opposed to having one Kansas licensed pharmacist as a responsible person for each company rather than having every non-resident PIC licensed in Kansas. However, this would require each company to provide us with the name of each non-resident pharmacy that they have responsibility over. We would be more than happy to work with these non-resident pharmacies so that they can provide us with up to date information and a current responsible person that would be available to the Board. The responsible person should have knowledge of how the regulatory board works and what authority it has over the pharmacy. This is a problem for the Board and in ensuring compliance but we are open to hearing of other ways that this issue could be resolved.

Thank you for permitting me to testify regarding this bill. I will be happy to yield to questions that anyone may have.



TESTIMONY

Concerning Senate Bill 549

Continuous Quality Improvement and Non-Resident Pharmacies

Before the SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

Presented by Michael F. Larkin, Executive Director
KANSAS PHARMACISTS ASSOCIATION

February 20, 2008

Chairman Barnett and Members of the Committee:

My name is Mike Larkin, and I am the Executive Director of the Kansas Pharmacists Association. The Kansas Pharmacists Association is a state professional society of pharmacists, united for, and dedicated to, the advancement and promotion of quality public health. The Kansas pharmacists Association is the only state-wide Association that represents Kansas pharmacists within all practice settings. The Kansas Pharmacists Association is also a member of the Kansas Pharmacy Coalition, an organization that is comprised of the Kansas Pharmacists Association and the Kansas Association of Chain Drug Stores.

I am before you today to speak in favor of Senate Bill 549. One of the reasons for existence of the Association is a commitment by member pharmacists to protect and advance the interests of the citizens of Kansas in the area of pharmacotherapy. Everyone in pharmacy recognizes the need to reduce prescription errors to the lowest level possible level. Almost everyone accepts that to do so, the pharmacy needs to adopt a plan. That plan, most acknowledge, should incorporate pharmacy best practices. We feel that Senate Bill 549 greatly assists us in this endeavor. The bill as written allows pharmacies to assess the errors that occur in the pharmacy free of being subject to punitive action that otherwise may be allowed through discovery. The Association feels this aspect of the bill is crucial to its success.

The one part of the bill that we would ask be changed is the implementation date. Senate Bill 549 currently indicates that January 1, 2009 would be the latest date a pharmacy could implement a CQI plan. We ask that the date be changed to July 1 2009. This is so that the Association can help educate its members and all interested pharmacists in the rules and regulations that will be promulgated by the board of pharmacy.

The Kansas Pharmacists Association fully supports the amendment of K.S.A. 65-1657 nonresident pharmacy registration in its current form.

Thank you for allowing me testify today I stand ready for any questions you may have. Thank you.

HEIN LAW FIRM, CHARTERED

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Ronald R. Hein

Attorney-at-Law

Email: rhein@heinlaw.com

**Testimony re: SB 549
Senate Public Health and Welfare Committee
Presented by Julie J. Hein
on behalf of
Kansas Pharmacy Coalition
February 20, 2008**

Mr. Chairman, Members of the Committee:

My name is Julie Hein, and I am government affairs consultant for the Kansas Pharmacy Coalition (KPC). The Kansas Pharmacy Coalition is an ad hoc coalition comprised of the Kansas Pharmacists Association and the Kansas Association of Chain Drug Stores.

The Kansas Pharmacy Coalition shares the public's interest in patient safety and reducing preventable errors. We recognize that pharmacy CQI programs can serve to meet this important goal. However, we are concerned that the legal protections afforded to pharmacy CQI programs in the bill do not sufficiently protect and maintain the confidentiality of program activities, proceedings and reports in a manner that is equitable to the protections afforded to other healthcare providers under K.S.A. 65-4915. We respectfully ask that the bill be amended to address this key concern before the bill is passed out of committee.

Pharmacy CQI program participants must feel free to candidly discuss incidents without fear of punitive repercussions.

In order for pharmacy CQI programs to serve the intended purpose of "assess[ing] errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence," participants of CQI programs must feel free to candidly discuss incidents without fear of punitive repercussions. Such an environment is essential for any pharmacy CQI program to be effective. By enabling pharmacy personnel to focus on the lessons and information learned, both the public and the practice of pharmacy will benefit from the resulting improvements.

As written, we are concerned that this language does not create the protections necessary to foster an environment where individuals feel free to candidly discuss incidents and other matters pertinent to pharmacy CQI activities. For this reason, we ask that language be inserted (mirroring that in K.S.A. 65-4915 (c)) which specifies that any pharmacy CQI program reports, records or discussions used in board administrative hearings be done so only in closed session. Further, all such proceedings and records thereof would not be subject to discovery, subpoena or other means of legal compulsion for release to any person or entity. Additionally, we ask that language be added (mirroring that in K.S.A. 65-4915 (c)) to clarify that the Board of Pharmacy may review peer review committee records, testimony or reports, *but* must prove its findings with independently obtained

PUBLIC HEALTH AND WELFARE

DATE:

ATTACHMENT:

02/20/08

testimony or records presented as part of the disciplinary proceeding in open meeting of the licensing agency (not solely through proceedings where CQI program records or activities were discussed). Both of these revisions will promote an environment in which participants in pharmacy CQI programs feel free to openly discuss incidents and pharmacy processes without fear of punitive repercussions.

Provide pharmacy CQI programs and the pharmacy personnel who participate in such programs with the same peer review protections that are afforded to other healthcare providers under existing Kansas Statute 65-4915.

As written, the bill does not afford pharmacists the same spectrum of protections that are given to other healthcare providers in the section 65-4915 (c) of the existing Kansas peer review laws. While the bill does establish some degree of peer review protections for the proposed pharmacy CQI programs, by comparison, statute ensures that peer review records of other healthcare providers including doctors, dentists, dental hygienists, nurses, practical nurses, mental health technicians, physical therapists, physical therapist assistants are protected from discovery if discussed in a licensing board proceeding. Statute also provides that such licensing boards may not use peer review records and proceedings as the sole source of evidence for bringing administrative actions against a licensee. We ask that pharmacy personnel be provided the same protections that are given to other healthcare professionals. As explained above, these protections are *imperative* for any pharmacy CQI program to effectively serve its purpose.

The Kansas Pharmacy Coalition thanks you for your consideration of the concerns that we presented to you and look forward to working with Senator Schmidt, the members of this committee and the Kansas Board of Pharmacy to resolve our remaining concerns.

Thank you very much for permitting me to testify, and I will be happy to yield to questions.

Polsinelli

Shalton | Flanigan | Suelthaus PC

Memorandum

TO: THE HONORABLE JIM BARNETT, CHAIR
SENATE PUBLIC HEALTH & WELFARE COMMITTEE

FROM: WILLIAM W. SNEED, LEGISLATIVE COUNSEL
EXPRESS SCRIPTS

RE: S.B. 549

DATE: FEBRUARY 20, 2008

Mr. Chairman, Members of the Committee: My name is Bill Sneed and I represent Express Scripts, one of America's largest pharmacy benefit managers, providing the pharmacy benefit for millions of people nationwide through employers, managed care plans, unions and governmental entities. Express Scripts is a company dedicated to making the use of prescription drugs safer and more affordable for plan sponsors and over fifty million members and their families. We appreciate the opportunity to present testimony on S.B. 549. We appear today in opposition to S.B. 549, but believe if the Committee would be willing to consider an amendment which we believe will answer some of the concerns raised by the filing of S.B. 549, we would be in a position to support the legislation.

S.B. 549 would create the requirement that an out-of-state pharmacy designate a pharmacist in charge who has a license from the Board of Pharmacy to engage in the practice of pharmacy in the State of Kansas. When K.S.A. 65-1657 was enacted, it was a carefully balanced bill of requiring nonresident pharmacies to comply with certain requirements and regulations, but hopefully not to the extent that it would substantially raise the cost of doing business, thus increasing the cost of pharmacy benefits. The amendment found on page 2, line 37, was thoroughly discussed by the legislative committees when K.S.A. 65-1657 was enacted, and was rejected due to the belief that this requirement is onerous and would lead to additional costs that would ultimately be borne by the consumer.

Additionally, creating such a requirement is extremely impractical for a variety of reasons. For example, if an out-of-state pharmacy hired a Kansas pharmacist and designated that person as a pharmacist in charge, and that individual left, it would take some time to get another individual properly licensed by the State of Kansas. These gaps would in fact occur, and ultimately this situation would harm our customers who are trying to provide pharmacy benefits.

It has been brought to our attention that the issue driving this proposal is the difficulty that the Board of Pharmacy is having in getting responses from out-of-state pharmacies. We

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PUBLIC HEALTH AND WELFARE
DATE:
ATTACHMENT:

02/20/08
6

understand that could be a problem and we support action taken by the Board of Pharmacy that would put some "teeth" in requiring responses by out-of-state entities. To that end, we would respectfully request that the Committee consider the following.

On page two, line 26, we would suggest amending K.S.A. 65-1657(b)(4), and at line 28 adding the following language.

"If, after receiving notice by certified mail, any person fails to file any report or other information with the board as required by statute or fails to respond to any proper inquiry of the board, the board, after serving notice and affording an opportunity for hearing, may impose a penalty of up to \$1,000.00 for each violation or act."

With that amendment, the Board of Pharmacy would then have the ability to seek redress with any out-of-state pharmacy that fails to respond to an appropriate inquiry. Thus, with this amendment, the new language found on page two, lines 6-8 and lines 37-43, and on page 3, lines 1-2, should be removed, thus creating a system whereby the Board has some regulatory oversight in getting responses to appropriate inquiries.

We appreciate the opportunity to present testimony on this bill, and we would be happy to answer questions at your convenience.

Respectfully submitted,



William W. Sneed

WWS:kjb



Your rights. Our mission.

To: Senator Jim Barnett, Chairman
Members of the Senate Public Health & Welfare Committee

From: Steven J. Borel, Attorney at Law
On behalf of the Kansas Association for Justice

Date: February 20, 2008

Re: SB 549 Pharmacy CQI Programs—**OPPOSE**

The Kansas Association for Justice is a statewide, nonprofit organization of attorneys that serve Kansans seeking justice. I appreciate the opportunity to testify on behalf of KsAJ on SB 549. KsAJ is opposed to SB 549, without the adoption of our amendment to correct its constitutional defects.

KsAJ supports policies that will have the effect of improving the quality of patient care and reducing patient injury. KsAJ was contacted by the Kansas Board of Pharmacy regarding their desire to seek passage of legislation requiring a mandatory "continuous quality improvement" (CQI) program for Kansas pharmacists. We appreciate their invitation to discuss this important issue prior to the formal legislative process, and their proactive efforts to improve the practice of pharmacy in Kansas.

SB 549 as drafted establishes a peer review privilege for pharmacists, similar to the privilege established for physicians and other health care providers in KSA 65-4915. Under the peer review privilege as it applies to physicians, documents and information generated as part of the peer review process are confidential and not subject to discovery in litigation. What this means is that privileged peer review documents are hidden from public view, including from the court and the jury, even if they contain evidence of medical negligence or a deviation from the standard of care.

However, the peer review privilege contains an important exception. In the Kansas Supreme Court decision of *Adams v. St. Francis Regional Medical Center*, 264 Kan. 144, 955 P.2d 1169 (1998), the court held that citizens have a constitutional right to factual information related to their case, and such information cannot be shielded by the peer

review privilege. The decision makes sense: if there were no limits on the peer review privilege, an incompetent, unethical, or negligent health care provider could intentionally hide all evidence of their actions from the patients that they injured to avoid accountability.

SB 549 does not currently reflect the important exception established in the *Adams* case and is therefore unconstitutional. Without clarification, SB 549 would create confusion about the discoverability of all the factual information normally included in a standard pharmacy incident report and all other factual information provided under the CQI program. This confusion would result in more litigation, which would not benefit either party to a dispute.

We propose the following amendment to clarify that the constitutional right to information confirmed in the *Adams* case also applies to pharmacy CQI programs: replace the final sentence at the end of new section 1, subsection (b) with the following language: "Nothing in this act shall affect the discoverability of facts relevant to any civil action for damages arising out of an incident or adverse event."

Without our amendment to correct the bill's constitutional flaws, we must oppose SB 549. We suggested our amendment to the Board of Pharmacy last week and hope that they agree that it is a reasonable and necessary clarification.

We note that, in considering the policy of SB 549, the Legislature must make an important decision regarding whether to extend a peer review privilege to pharmacists, such as that created in section 1, subsection (b) of SB 549. The "peanut" of SB 549 is to establish peer review protections for pharmacists, since the Board of Pharmacy could otherwise require a CQI program through rule and regulation and without legislation. But the Legislature has made a policy decision not to include pharmacists in the list of healthcare providers covered by the Kansas statute that establishes the rules and the terms of peer review privileges for healthcare providers (KSA 65-4915).

KsAJ believes a broad application of the peer review privilege is not in the best interests of Kansas health care consumers and in fact would be very dangerous. We believe the current peer review statute is already too broad: it includes mental health technicians, physical therapists and physical therapist assistants, occupational therapists and occupational therapist assistants, respiratory therapists, physician assistants, and attendants and ambulance services. We believe these professionals, who neither diagnose nor treat patients, are clearly unlike physicians.

KsAJ is firmly opposed to a broad expansion of the peer review privilege across the spectrum of the health care industry. Not all health care professionals, or those in the health care industry, require a peer review privilege to improve the quality of their services to the public. The peer review privilege is an enormous barrier to transparency and infringes upon the public's right to information. By extending a peer review privilege to pharmacists, the Legislature will open the door to a broader section of the health care industry including nursing homes that will also want a peer review privilege.

We ask that the Committee proceed cautiously in advancing SB 549 given this important public policy issue and the potential to create a "slippery slope" that would hurt Kansas patients. We respectfully request that if the bill advances that it be amended to include our proposed amendment.

Thank you for the opportunity to present testimony.

**CONTINUOUS QUALITY IMPROVEMENT
TASK FORCE
MINUTES OF THE MEETING**

October 10, 2007
Kansas Pharmacists Association
1020 SW Fairlawn
Conference Room
Topeka, KS

Tuesday, October 10, 2007

PERSONS PRESENT: Michael Coast, R.Ph., Board of Pharmacy; JoAnne Gilstrap, R.Ph., Board of Pharmacy; Frank Whitchurch, R.Ph., Board of Pharmacy; Randall Forbes, General Counsel for Board of Pharmacy; Reyne Kenton, Board of Pharmacy; Melissa Martin, Board of Pharmacy; LaTonyua Rice R.Ph, Wichita Academy of Pharmacists and Target, Senator Vicki Schmidt R.Ph.

MEETING CALLED TO ORDER: Frank Whitchurch, R.Ph. called the meeting to order at 9 a.m.

The group discussed the importance of CQI and that it would be appropriate to recommend to the Board of Pharmacy to move forward with creating a statute that is similar to Florida's or Iowa's and to draft a regulation. The group was in favor of using Iowa's regulation as a starting point in creating the language for the regulation.

The group discussed the importance of the records being non-discoverable and how standard practice of peer review played a role in what records are protected. It was decided based on *Adams v. St. Francis* that the new statute should protect all but the facts from discovery but would make everything available to appropriate authorities. A meeting with the Trial Lawyers to discuss the statute and view the proposed regulations will be scheduled when ready. Senator Schmidt agreed to help the board with the legislative process and will continue to assist with drafting the statute and regulations.

The group discussed if paper documents would be required or an electronic source would be acceptable. If an electronic source were decided upon, which based on testimony from our group seemed the desirable approach, then a time period would need to be set for producing the records. A 72-hour period of time was suggested. There was discussion on how often practice based QI meetings should occur regarding these reports. At least quarterly was agreed upon and to require these meetings to be documented.

The group discussed amending the incident report regulation and to define what an incident is and then decided after much discussion that the incident report would not be necessary when the CQI process is in place. The group decided that revoking the incident report regulation and letting CQI take the place of the incident report requirement would be appropriate. Iowa's law defines what a reportable event is and it

was agreed upon that the definitions were acceptable. The group decided to go forward with a CQI statute which Randy will author and email out to us for comment. The next step would be to draft regulations which the group will address at the November 7th meeting.

The group discussed what time period would be given for implementation of a CQI program. Anywhere from 3 months to 6 months were discussed from the date of the regulation becoming law.

The next meeting was scheduled for 9 a.m. on November 7, 2007 at the Kansas Pharmacists Association. The plan is that at the end of this meeting the task force will be able to have a completed statute and regulations to present to the full board for consideration. The next step is to determine the timeline to send to legislature and meet with the trial lawyers.

**KANSAS STATE BOARD OF PHARMACY
MINUTES OF THE MEETING**

December 17 & 18, 2007
US Bank Building
800 SW Jackson
Topeka, KS

Monday, December 17, 2007

MEMBERS PRESENT: Michael Coast, RPh., President; Dr. Shirley Arck, Pharm.D., Vice President; JoAnne Gilstrap, R.Ph.; Frank Whitchurch, R.Ph.; Karen Braman, R.Ph., M.S.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Carly Haynes, R.Ph. Pharmacy Inspector; Melissa Martin, Compliance Officer; Randall Forbes, General Counsel; Derenda Mitchell, Assistant Attorney General; and Lori Thompson, Administrative Assistant.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: President Michael Coast called the meeting to order at 9:00 a.m.

APPROVAL OF AGENDA. A motion was made and seconded to approve the agenda (Whitchurch/Arck). Motion carried 4-0.

APPROVAL OF SEPTEMBER MINUTES A motion was made and seconded to approve the September 2007 minutes. (Arck/Gilstrap). Motion carried 4-0.

AVAILABILITY OF LEAF MARIJUANA FOR MEDICINAL PURPOSES.

Presented by Dr. Eric Voth, MD, FACP

Dr. Voth is the chairman of The Institute on Global Drug Policy. He presented a power point presentation related to the safety implications of using leaf marijuana for medicinal uses. The Department of HHS, including the FDA has previously concluded that no sound scientific studies support medical use of marijuana for treatment in the United States. Accordingly, the FDA and DEA do not support the use of smoked marijuana for medical purposes. Dr. Voth provided that there are safe and effective reliable medicines that do exist that are best for patients. He requested that the Board of Pharmacy pass a resolution taking the position that the Board of Pharmacy does not approve of leaf marijuana for medicinal purposes. A motion was made and seconded to pass a resolution that until approved by the FDA the Board of Pharmacy does not support the use of leaf marijuana for treatment of any medical condition. (Braman/Gilstrap). Motion carried 4-0.

ADMINISTRATIVE PROCEEDINGS

KATIE SUROWSKI, R.Ph. Case No. 07-52

The Respondent appeared in person. The Board was represented through its counsel, Assistant Attorney General Derenda Mitchell. The proposed discipline was a Consent Agreement which will provide for the standard CIPP requirements for a period of five years. A motion was made and seconded to accept a Consent Agreement and the Board directed the Assistant Attorney General to draft said agreement for signature by all parties. (Braman/Whitchurch). Motion carried 3-0.

WASHINGTON HEALTHMART Case No. 07-32

The Respondent did not appear. The Board was represented through its counsel, Assistant Attorney General Derenda Mitchell. The Board was provided with a Consent Order. The proposed discipline was a fine of \$500 for failing to maintain a completed incident report. The Board requested that this matter be carried over to the next meeting and that the Respondent provide a copy of a completed incident report as well as a policy and procedure manual.

WALGREENS Case No. 07-20

The Respondent did not appear. The Board was represented through its counsel, Assistant Attorney General Derenda Mitchell. The Board was provided with a Consent Order. The proposed discipline was a fine of \$500 for failing to maintain a completed incident report. A motion was made and seconded to accept the Consent Agreement. (Braman/Gilstrap). Motion carried 3-0.

INVESTIGATIVE REPORT

Presented by Shirley Arck, Pharm.D., Vice-President/Investigative Member

The Board reviewed closed cases.

DISCUSSION REGARDING EMERGENCY KITS

The Board had requested a legal opinion regarding the permissibility of the use of an Emergency Medication Kit ("E-Kit") in an assisted living facility. The Pharmacy Act permits an Adult Care Home to maintain an E-Kit. An assisted living facility falls under the definition of an Adult Care Home so they may utilize an E-Kit. However, the assisted living facility shall maintain the E-Kit in compliance with the following requirements: 1) Drugs in the E-Kit shall be maintained under the control of the pharmacist-in-charge of the pharmacy from which the kit came until administered to the patient upon the proper order of a practitioner. 2) Drugs may include controlled substances, but in such cases a pharmaceutical services committee shall be responsible for specifically limiting the type and quantity of controlled substances that are placed in the E-Kit. 3) Administration of controlled substances shall be in compliance with the Uniform Controlled Substance Act. 4) The consultant pharmacist shall be responsible for developing procedures, proper control and accountability for the E-Kit and shall maintain accurate records of the controlled substances. A periodic physical inventory of the kit is required.

Further, the assisted living facility would need to utilize the services of a pharmacist and the E-Kit would have to be approved by the medical staff composed of a duly licensed practitioner and a pharmacist. The Emergency Kit could only be used in cases of emergency and can only be accessed by a licensed registered nurse or nurses or licensed practitioner.

A related question was whether an assisted living facility could fax a C-II prescription the same as a long term care facility. They cannot. The Controlled Substance Act limits faxed schedule II prescriptions to long term care facilities only. The Board attorney was also asked whether drugs could be returned from an assisted living facility.

KAR 68-12-2 specifically states that prescription drugs may not be resold, redispensed, or distributed unless the prescription drug is in a single unit dose package containing only one medication and in which the drug has not been dispensed to the final consumer or reached the patient. The package must also be intact. Since most patients in an assisted living facility maintain their own medications this regulation would not generally apply to their situation and their drugs could not be returned to the pharmacy.

The Board also discussed whether an infusion clinic met the requirements for an E-Kit. Infusion pharmacies are not always located on the premises of the clinic and there were concerns that a patient may find themselves in an emergency situation in which an E-Kit would be helpful. If the clinic were licensed as a Home Health agency they would fall under the provisions of K.S.A. 65-1659 and would be permitted to carry sterile water for injection or irrigation; sterile saline solution for injection or irrigation; heparin flush solution; diphenhydramine injectable; and epinephrine injectable. It is unlikely that they have been deemed to be a home health agency. Therefore, their options may be limited. The infusion clinic can call 911 in the case of an emergency or the physician can write an order for the patient ahead of time and have it filled and the patient can keep the drugs with them at all times. These are not particularly good solutions. The Board will contact KDHE, Aging and any other applicable licensing authority and schedule a meeting. It is possible that something could be worked out that would provide for better patient care. Steve Schwarm will also be notified of the meeting so that he can attend.

DISCUSSION REGARDING BOARD STRATEGIC PLAN

Frank Whitchurch provided the Board with a copy of the California State Board of Pharmacy Strategic Plan. It addressed that Board's vision and mission statement, strategic issues to be addressed such as costs of pharmaceutical care, aging population, pharmacists' ability to provide care, changing demographics, laws governing pharmacists, integrity of the drug delivery system, technology, internet issues, disaster planning, qualified staff and Board members and pharmacy health care in the 21st century. Frank suggested that the Kansas Board have a retreat sometime this spring and that they set goals in anticipation of planning for future events and issues. The Board agreed that this would be beneficial and directed the Executive Secretary to schedule a spring meeting specifically for strategic planning

DISCUSSION REGARDING JOINT MEETING OF KANSAS STATE BOARD OF HEALING ARTS (KSBHA) AND KANSAS BOARD OF NURSING (KSNB) RELATED TO PRESCRIPTIONS WRITTEN BY PHYSICIAN ASSISTANT (PA) AND ADVANCED REGISTERED NURSE PRACTITIONER (ARNP)

Shirley Arck advised the Board that she, Frank Whitchurch and Deb Billingsley attended the December 7, 2007 Joint Meeting of the KSBHA and the KSNB. The Board of Pharmacy addressed the two Boards regarding the statutes and regulations related to prescriptions written by PA's and ARNP's that require the name, address and telephone number of the responsible physician on each actual prescription. The KSBHA and KSNB both indicated that there was no patient safety issues that would require the responsible physician's name to be on the prescription. Therefore, they agreed to work with the Board of Pharmacy on making changes in their laws that would be consistent with each agency. The Board staff did subsequently contact the KSBHA and asked them whether a prescription would be valid if the PA failed to indicate the responsible physician's name, address and telephone number and the KSBHA said it would not be valid. Therefore, the Board of Pharmacy determined that it would not be beneficial to change the labeling requirements unless the KSBHA and KSNB change their statutory and regulatory requirements regarding the requirements of a valid prescription. The Board of Pharmacy will continue to work with KSBHA and KSNB on this issue.

RECESS: A motion was made and seconded to recess for lunch until 1:30 p.m. Motion carried 4-0.

BACKGROUNDING OF LICENSEES AND REGISTRANTS

The KSBHA and KSNB have both tried to get legislation passed that would permit backgrounding and fingerprinting of their licensees. This has been difficult to get passed in the legislature. KSBHA Executive Director, Larry Buening reported to his Board that Post Audit was recommending that licensing boards pass legislation that would require fingerprinting and backgrounding of licensees. The Board of Pharmacy would like to explore this option also but will wait to see whether the legislature is favorable toward KSBHA and KSNB. The Board of Pharmacy staff will get a copy of the Post Audit Report for the Board members.

DISCUSSION REGARDING PEDIGREE AND WHOLESALE LICENSURE

The Board was provided with draft regulations related to wholesale distributors. The Board counsel drafted the regulations based on discussions from the previous task force of stakeholders related to wholesale distribution. The Board discussed some specific issues related to confidentiality and open records with the Board General Counsel. They advised Randy Forbes to move forward with the regulations.

The Board also reviewed the language of the Illinois Pedigree statute that was recently passed in that state. The Board directed the Board attorney to use the Illinois language as a model toward drafting additional pedigree regulations. The Board will meet again on January 9 to discuss the draft regulations.

DISCUSSION REGARDING COMPOUNDING REGULATIONS

Shirley Arck, Pharm.D. reported that she had participated in a phone call with Pat Parker, R.Ph., Jeff Thompson, R.Ph. Debra Billingsley, Randy Forbes and Lane Hemsley on November 19, 2007 to review the latest draft of the compounding regulations. Since that phone conference the USP revised various areas of Chapter 797. Pat Parker advised the Board of the specific changes that had been made to Chapter 797 and he suggested that the Board consider making revisions to their Compounding draft. The Board agreed and recommended that Randy Forbes reference the USP 797 changes in the draft regulations. The group agreed to have another phone conference to review the amendments made to the draft. All Board members will be notified when the phone conference will be held. As soon as the committee approves the changes to the draft it can be sent to the Dept. of Administration for their approval.

RECESS: A motion was made and seconded to recess until 3:42 p.m.

RECONVENE: The President reconvened the meeting at 3:42 p.m.

DISCUSSION REGARDING TECH CHECK TECH PROGRAM

The Board was addressed by Pat Parker, R.Ph., of Lawrence Memorial Hospital, Eugene Dedonder, R.Ph. of Newman Memorial County Hospital, and Kirk Starr of St. Francis Health Center regarding their use of the tech check tech program as it relates to filling the pyxis machine and other automation systems. The Board was considering whether regulations needed to be written that would actually permit this function. The Board was given statistical information related to errors, advised how data was collected, and how the technicians were monitored for accuracy. The Board determined that this was something that needed to be in the medical facility pharmacy regulations and they directed the Board attorney to draft language. Once the language is drafted it will be sent to interested parties and the Board Executive Secretary will discuss whether the regulations will meet the needs of hospital pharmacists.

**DISCUSSION REGARDING AUTOMATED PRESCRIPTION SYSTEM
PARATA SYSTEMS**

Bill Holmes of Parata Systems attended the Board in order to provide additional information that had been requested at the last Board meeting. This system was requested by Wal-Mart pharmacy and the automation would be located in the pharmacy used only for refills. It would not contain any controlled substances. It was suggested that this should only be used when the actual pharmacy is open for business otherwise it will be closed. Mr. Holmes provided the Board with a written resolution and asked that the Board approve the system. The Board will have their attorney review the resolution. The Board needs to determine whether policies can be put in place that would address this type of automation. This matter should be carried to the January 9, 2008 meeting for further discussion and possible approval.

INSTYMEDS SYSTEM

Matt Sneller, Pharm.D., Vice President of Pharmacy Operations for InstyMeds, Martie Ross of Lathrop and Gage Law Firm, Christy Keating, RN, Craig Campbell, R.Ph. and Jay Allen, MD of Mercy Health Center in Fort Scott, Kansas asked the Board for approval of the Instymeds System in Kansas. Particularly, Mercy Hospital in Fort Scott would like to use the system in their hospital. The machine would be located in the emergency room and contains mostly generic acute medications. It would contain controlled substances. It would allow the physician to write a prescription and the physician would counsel the patient. The patient would then pay retail through the automation and would receive no more than a 30 day supply. The group discussed the needs of the hospital and the safety features of the machine. The Board did not make a decision on whether to approve Instymeds. The Board needed additional time to study the issue and to determine whether the telepharmacy regulations would assist the hospital with their particular problems. This matter would be discussed at the next available Board meeting.

ADJOURNMENT: A motion was made and seconded to adjourn until 9:00 a.m. on Tuesday, December 18, 2007. Motion carried 4-0.

Tuesday, December 18, 2007

MEMBERS PRESENT: Michael Coast, R.Ph., President; Shirley Arck, Pharm.D., Vice-President; JoAnne Gilstrap, R.Ph., Frank Whitchurch, R.Ph., Karen Braman, R.Ph., M.S.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer, Lane Hemsley, General Counsel; and Lori Thompson, Administrative Assistant.

OTHERS PRESENT: See Attached Listing.

MEETING CALLED TO ORDER:

President Coast called the meeting to order at 9:00 a.m.

ADMINISTRATIVE PROCEEDING:

JAY PARKER, R.Ph. Case No. 07-81

The Respondent appeared in person and through his counsel, Darin Conklin of Alderson, Alderson, Weiler, Conklin, Burghart, & Crow, LLC. The Board was represented by Lane Hemsley of Frieden and Forbes, LLC. The matter was before the Board on an application for a pharmacist reinstatement. A motion was made and seconded to go into executive session to deliberate until 10:45 a.m. (Whitchurch/Arck). Motion carried 4-0. The Board reconvened and a motion was made and seconded to go into executive session to deliberate until 10:50. (Whitchurch/Arck). Motion carried 4-0. The Board reconvened at 10:50 a.m. A motion was made and seconded to enter an Order issuing the Respondent a pharmacist license with the restrictions that he be placed on probation for 2 years

beginning December 18, 2007. During the probationary period the Respondent will continue his criminal case probation and provide a statement from his probation officer that he has successfully completed the requirements upon completion. The Respondent will be restricted and cannot be a Pharmacist in Charge or a pharmacy owner. The Board will receive quarterly reports from the therapist for the next two years. The Board directed Lane Hemsley to draft the Order with the above stated conditions. (Braman/Gilstrap). Motion carried 4-0.

DISCUSSION REGARDING CLASSIFICATION OF PHARMACIES

a. Nuclear Pharmacy Regulations

Frank Whitchurch reported that he had met with interested stakeholders and discussed the different varieties of pharmacies that the Board licenses. As part of the discussion it was determined that a definition for consultant pharmacist needed to be added to K.S.A. 65-1626. Oversight of the newer pharmacy practice modalities is largely dependent upon the inspector's application of current statutes and regulations that were designed for typical retail or medical care facilities. Regulations need to be written for the newer practice modalities such as nuclear pharmacy, Methadone clinics, long term care pharmacy, same day surgery centers, non-drug pharmacy or consultant pharmacies, and mail order pharmacy.

The group worked on nuclear regulations that are similar to Oklahoma regulations. The Board discussed the issue of nuclear pharmacy technicians and whether the regulations should address the ratio issue. The question was whether the nuclear training certification has a standard not below that of PTCB. Becca Baugher offered to obtain information on nuclear pharmacy technician training so that the Board could review whether this certification would allow for the three to one ratio.

b. Prescription vs. Medical Order requirements

Frank Whitchurch further advised the Board that while reviewing the classifications of pharmacy issue that it was apparent that medical facilities had exempted themselves from requirements without having anything in the regulations so stating. The Board reviewed the useful information and directed the Executive Secretary to ask KPhA to remove the statement in the law book that relates to prescriptions versus medical orders as there is no legal authorization for the statement. The Board has not taken the position that medical facilities are exempt and the law book should not have a statement in it that states otherwise. Staff will continue to work on classification of pharmacy and will submit a plan to the Board for approval.

DISCUSSION REGARDING CQI

The CQI Committee met in October and November. They worked on a draft statute and regulation related to incident reports. The group discussed the current requirements for an alleged or real error in filling or dispensing. They were able to define an incident as a preventable medication error resulting in the incorrect dispensing of a prescription as a result of a series of risks. The series of risks were included in the proposed regulation. They also determined by regulation what should be in the incident report. The Committee recommended that the Board move toward an enabling statute and regulation

related to CQI. Once that is in place then the current incident report regulation should be amended. A motion was made and seconded to move toward taking the necessary steps to implement CQI. (Whitchurch/Gilstrap). Motion carried 4-0.

DISCUSSION REGARDING PRESCRIPTION DRUG MONITORING PROGRAMS AND SUDAFED PRODUCT MONITORING

The Controlled Substance Task Force has been meeting periodically. They have draft legislation for both a prescription drug monitoring program and a Sudafed tracking program. The group will be meeting again at 2:00 on December 18. Mike Coast went to a meeting in Washington D.C. that was sponsored by the Dept of Justice and the Model Drug Laws. He was able to get a lot of information regarding these programs and the grant money that is available.

DISCUSSION REGARDING DONATED DRUGS

The Board reviewed HB 2578 related to donating drugs. This language was taken from Oklahoma but their pharmacies are government owned. The Board decided that it would best to amend the Cancer Drug Repository statute and to submit it as a substitute bill. The Board would like Rep. Kay Wolf notified so that she will know that the substitute bill is in support of donating drugs. It would permit donations within a model that works in Kansas rather than the one in Oklahoma which does not support any model in this state. The Board supports the bill in theory but have problems with implementation.

SHARED SERVICES

The Board reviewed the shared services regulation and how this would work for those pharmacists working from home. The Board staff was directed to put their concerns about licensing and regulating persons from their home. The Board would also like to know how other states are handling the issue of consultant pharmacists and whether they are licensing them as a separate classification. Board staff will report back to the Board on this particular issue.

BOARD MEMBER REPORTS:

Shirley Arck, Pharm.D. recommended that the Board look into going electronic for their Board packets. The Board of Nursing is using laptop technology and it would cut down on the amount of paper that is currently dispersed. This would also permit the Board to implement a cut off date for submitting information that could be downloaded to the Board packet. The Board agreed that this should be pursued.

Shirley also thanked the inspectors for their hard work on developing the cases. She appreciated the efforts that they put into their disciplinary cases.

JoAnne Gilstrap, R.Ph. recommended that the Board report the DEA rule regarding the issuance of multiple prescriptions for schedule II controlled substances in the next newsletter. This should also be on the agency website.

Ms. Gilstrap also reported that there were many epileptic drugs that were going to become generic. Many drug companies are going to state legislatures to ask for more restrictions. Before you can substitute you would have to go through extra steps. She recommended that the Board watch for this issue and to make sure that the Board provided information to the legislature regarding this issue should it arise.

The December Board meeting was canceled due to the weather and Ms. Gilstrap advised the Board that she felt that this was the right thing to do. However, she would like to make sure that in the future we try to schedule the December Board meeting in late November or early December to avoid holiday conflicts.

Ms. Gilstrap asked if the Board office was approving Continuing education. The Board staff has continued to review CE requests on a case by case basis.

Michael Coast, R.Ph. advised the Board that he, Carly Haynes, R.Ph. and Deb Billingsley attended the KPhA annual meeting in Hutchinson, Kansas. The KPhA members provided feedback that they felt that more board members should try to attend the meeting if possible. Mike agreed and stated that KPhA's next annual meeting would be the September 28, 2008 and that everyone should try to attend.

Mr. Coast also thanked the Board inspectors for all of their hard work.

EXECUTIVE SESSION – PERSONNEL

The Board adjourned into executive session to discuss personnel issues until 1:00 p.m.

STAFF REPORTS

Carly Haynes, R.Ph. advised that she had been reviewing other states regulations. Almost all states require nonresident pharmacies to be licensed before they can ship into their state. She also thought it was interesting how each state viewed the job of the inspector. Many states permit the inspector to issue a ticket related to minor offenses such as violation of the technician ratio.

Debra Billingsley reviewed the current status of regulations that the Board is working on.

KAR 68-2-20 related to a pharmacist's function in filling a prescription.

The Attorney General rejected the language. Randy Forbes wrote a letter to the AG disputing the AG's position. We are waiting to hear from the Attorney General's Office on their position.

KAR 68-7-14 Prescription Labels

The Board met with the Nursing Board and with the Board of Healing Arts. The Board of Healing Arts believes that before a prescription is valid that it must contain all information related to the PA/ARNP and their responsible physician. Therefore, the Board can change the labeling requirement but it will prevent a prescription from being

filled if the correct information is not on the actual prescription. The Board will meet again with the KSBHA and the KSBN.

KAR 68-7-19 Transfer of a refillable prescription

Randy Forbes sent a letter to the DEA asking for a legal opinion. He is waiting for that decision.

KAR 68-7-21 Institutional Drug Rooms

Scheduled for March meeting for public hearing.

KAR 68-11-2 Fees for DME Providers

Regulation has been drafted and sent to the Dept of Administration

KAR 68-13-1 through KAR 68-13-4 Compounding Regulations

The compounding task force will make revisions from latest USP changes. Amendment will be sent to the Dept of Administration.

KAR 68-7-1 through KAR 68-7-11 Telepharmacy Regulations

Regulations are under review at the Dept. of Administration

KAR 68-2-16 Branches Agents Pick Up Stations

Regulations are under review at the Dept. of Administration

KAR 68-20-23 Limit on Controlled Substances Dispensed

Scheduled for Public Hearing at March meeting.

The Board reviewed a letter from Senator Derek Schmidt on behalf of a constituent. The question has been raised by other patients also regarding putting the diagnosis on the prescription label. The Board advised that this would need to be something that the physician directed be on the label. We should refer this to the Board of Healing Arts and ask for their assistance.

ADJOURN. The Board adjourned their meeting at 1:45 p.m.



KATHLEEN SEBELIUS
GOVERNOR

STATE BOARD OF HEALING ARTS

LAWRENCE T. BUENING, JR.
EXECUTIVE DIRECTOR

February 19, 2008

The Hon. Jim Barnett
Chairman
Senate Committee on Public Health
and Welfare
Room 120 South
State Capitol

Re: Senate Bill No. 596

Dear Senator Barnett:

Thank you for the opportunity to appear before the Committee on behalf of the State Board of Healing Arts in support of SB 596. This Committee introduced the bill at the Board's request. The Board's purpose in requesting the bill was to define the term "surgery" and to clarify that surgical procedures are within the scope of the medicine and surgery profession even when performed solely for cosmetic or aesthetic purposes.

The current definition of the healing arts and of the practice of medicine and surgery, appearing at K.S.A. 65-2802 and 65-2869, respectively, describe professional services performed for the treatment or correction of diseases, injuries and deformities. In addition, there has been controversy in the past over what constitutes surgery. SB 596 would define surgery in definite terms and would clearly identify that cosmetic or aesthetic surgery is the practice of medicine and surgery, which is a branch of the healing arts. This definition is not intended to encompass acupuncture or manipulation, which are currently understood not to be surgery procedures.

The Board seeks clarification of the scope of surgery because surgical services are being used for cosmetic or aesthetic purposes, some of which are performed by physicians, and some of which are not. The purpose for seeking the service should not be the factor that determines whether licensure is required. Examples of surgeries that might or might not be for treating or correcting diseases, injuries or deformities include face lifts, breast augmentations or reductions, or liposuction. No serious argument has been advanced that these surgeries should be outside of the regulatory scheme. Other surgical procedures are performed that pose dangers to patients. I have attached pictures of a woman who is receiving a treatment called "scarification." Also attached is a picture of the end result of tongue splitting. Other procedures include implanting of materials and devices under the skin.

PUBLIC HEALTH AND WELFARE

DATE:

ATTACHMENT: 9

02/20/08

9

BOARD MEMBERS: BETTY McBRIDE, Public Member, PRESIDENT, Columbus - VINTON K. ARNETT, D.C., VICE PRESIDENT, Hays - MICHAEL J. BEEZLEY, M.D., Lenexa
MYRA J. CHRISTOPHER, Public Member, Fairway - RAY N. CONLEY, D.C., Overland Park - GARY L. COUNSELMAN, D.C., Topeka - FRANK K. GALBRAITH, D.P.M., Wichita
MERLE J. "BOO" HODGES, M.D., Salina - SUE ICE, Public Member, Newton - M. MYRON LEINWETTER, D.O., Rossville - MARK A. McCUNE, M.D., Overland Park - CAROLINA M. SORIA, D.O., Wichita
ROGER D. WARREN, M.D., Hanover - NANCY J. WELSH, M.D., Topeka - RONALD N. WHITMER, D.O., Ellsworth

235 SW TOPEKA BLVD., TOPEKA, KS 66603

Voice: 785-296-7413 Toll Free: 888-886-7205 Fax: 785-296-0852 Website: www.ksbha.org

State Board of Healing Arts
Senate Bill No. 596
February 19, 2008
Page 2

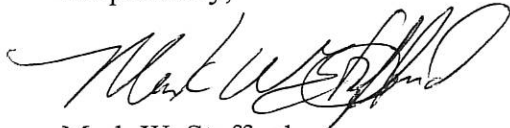
Section 3 of SB 596 also provides that non-surgical services performed by electrologists, licensed permanent color technicians and tattoo artists, or body piercers regulated by the Board of Cosmetology and acting within the scope of their licenses are not required to be licensed by the Healing Arts Board. Section 3 also includes some clean up of the introductory language, which currently states that the healing arts shall not be deemed to include the services of persons listed in that statute. The Board believes that those services do constitute the healing arts, as defined elsewhere in the act, but that the section merely creates exceptions from licensure by the Board.

Section 3 also deletes the word "referral" from subsection (g) of the statute. The reason for the requested deletion is the common misconception of the process for a referral. The term sometimes is used to mean the formal act of sending a patient for a specific treatment regimen to a person who would not have independent authority to treat, such as an occupational or respiratory therapist. The referral in that sense is based on the licensee's conclusions about the nature of the problem, and is an order for treatment. In other senses, the term is used less formally, such as directing the patient or recommending another person, and does not order treatment or imply the authorization. Yet that casual "referral" would currently allow that unlicensed person to diagnose and treat without a license, and there are no limitations on what services that person may perform.

Section 3 also includes technical modifications recommended by the Revisor of Statutes, and other statutes making reference to K.S.A. 65-2872 are amended accordingly.

Once again, thank you for the opportunity to appear before the Committee.

Respectfully,



Mark W. Stafford
General Counsel





9-4



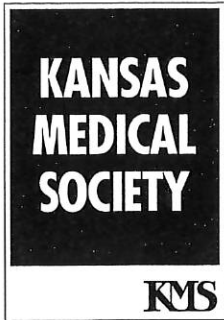


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To: Senate Public Health and Welfare Committee

From: Jerry Slaughter
Executive Director

Date: February 20, 2008

Subject: SB 596; concerning the performance of aesthetic or cosmetic procedures;
and definition of surgery

The Kansas Medical Society appreciates the opportunity to appear in support of SB 596, which amends the Healing Arts Act to clarify that the performance of surgical procedures for purely aesthetic or cosmetic purposes constitutes the practice of medicine and surgery as defined under the Act (page 2, lines 7-8). The bill also adds a definition of "surgery" to the Healing Arts Act (page 1, lines 36-41). Finally, the bill adds licensed electrologists, tattoo artists, and body piercers to the list of individuals that are exempt from licensure under the Act when licensed and practicing their profession pursuant to law (page 4, lines 1-6).

The principal effect of the bill would be to make it clear that certain "body modification" surgical procedures that are purely aesthetic or cosmetic, and not medically necessary, such as tongue-splitting (which is the central bifurcation of the tongue, so as to achieve a "forked tongue" appearance), may only be done by licensed physicians. Such procedures carry with them significant risk of complications, such as substantial tongue hemorrhage, abscess formation, tetanus and nerve damage. This legislation would make it clear that such procedures would constitute the practice of medicine and surgery, and thereby be subject to the Act (page 2, lines 7-8).

As part of that clarification, a definition of "surgery" would be added to the Healing Arts Act. We believe such a clarification is necessary and would be very helpful to the Board for enforcement purposes. We would like to offer a couple of suggestions to further clarify the proposed definition, and make it more consistent with the definition of surgery which appears in the Board's regulations governing office-based surgical procedures. Our suggested amendment to the definition of "surgery", found on page 1, at lines 36-41, appears below:

PUBLIC HEALTH AND WELFARE
DATE:
ATTACHMENT: 10

02/20/08
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(f) "Surgery" shall mean the use of any device, procedure or method to sever, remove, destroy or structurally alter body tissue or implant any device, object or tissue into the body of human beings for any purpose, including preserving health, diagnosing or treating disease, repairing injury, reducing closed or open fractures, correcting deformity or defects, prolonging life or relieving suffering, or for an aesthetic, reconstructive or cosmetic purpose. Surgery shall not be construed to mean manipulation for adjustment of misplaced tissue or acupuncture.

We would urge the Committee to adopt the definition, as amended above, and recommend the bill favorably for passage. Thank you for considering our comments.

SENATE BILL No. 596

By Committee on Public Health and Welfare

2-11

Senate Committee on Public Health and Welfare
Balloon Amendment Proposed by KMS
February 21, 2008

9 AN ACT relating to the board of healing arts; concerning cosmetic or
10 aesthetic purpose included in the practice; amending K.S.A. 65-2869
11 and 65-5514 and K.S.A. 2007 Supp. 65-2802, 65-2872, 65-2913 and
12 65-5418 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

15 Section 1. K.S.A. 2007 Supp. 65-2802 is hereby amended to read as
16 follows: 65-2802. For the purpose of this act the following definitions
17 shall apply:

18 (a) The healing arts include any system, treatment, operation, diag-
19 nosis, prescription, or practice for the ascertainment, cure, relief, pallia-
20 tion, adjustment, or correction of any human disease, ailment, deformity,
21 or injury, and includes specifically but not by way of limitation the practice
22 of medicine and surgery; the practice of osteopathic medicine and sur-
23 gery; and the practice of chiropractic.

24 (b) "Board" shall mean the state board of healing arts.

25 (c) "License" shall mean a license to practice the healing arts granted
26 under this act.

27 (d) "Licensed" or "licensee" shall mean a person licensed under this
28 act to practice medicine and surgery, osteopathic medicine and surgery
29 or chiropractic.

(e) "Healing arts school" shall mean an academic institution which
grants a doctor of chiropractic degree, doctor of medicine degree or doc-
tor of osteopathy degree.

~~(f) Wherever the masculine gender is used it shall be construed to
include the feminine, and the singular number shall include the plural
when consistent with the intent of this act.~~

(f) "Surgery" shall mean the use of any device, procedure or method
to sever, remove, destroy or structurally alter body tissue or implant any
device, object or tissue into the body of human beings for any purpose,
including an aesthetic, reconstructive or cosmetic purpose. Surgery shall
not be construed to mean manipulation for adjustment of misplaced tissue
or acupuncture.

Sec. 2. K.S.A. 65-2869 is hereby amended to read as follows: 65-
2869. For the purpose of this act the following persons shall be deemed

preserving health, diagnosing or treating disease,
repairing injury, reducing closed or open fractures,
correcting deformity or defects, prolonging life or relieving
suffering, or for

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11

PUBLIC HEALTH AND WELFARE
DATE:
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Sec. 1. K.S.A. 65-5402 is hereby amended to read as follows: 65-5402. As used in K.S.A. 65-5401 to 65-5417, inclusive, and K.S.A. 65-5418 to 65-5420, inclusive, and amendments thereto:

(a) "Board" means the state board of healing arts.

(b) "Practice of occupational therapy" means the therapeutic use of purposeful and meaningful occupations (goal-directed activities) to evaluate and treat, pursuant to the ~~referral~~ supervision, order or direction of a physician, a licensed podiatrist, a licensed dentist, a licensed physician assistant, or an advanced registered nurse practitioner working pursuant to the order or direction of a person licensed to practice medicine and surgery, a licensed chiropractor, or a licensed optometrist, individuals who have a disease or disorder, impairment, activity limitation or participation restriction that interferes with their ability to function independently in daily life roles and to promote health and wellness. Occupational therapy intervention may include:

- (1) Remediation or restoration of performance abilities that are limited due to impairment in biological, physiological, psychological or neurological cognitive processes;
- (2) adaptation of tasks, process, or the environment or the teaching of compensatory techniques in order to enhance performance;
- (3) disability prevention methods and techniques that facilitate the development or safe application of performance skills; and
- (4) health promotion strategies and practices that enhance performance abilities.

(c) "Occupational therapy services" include, but are not limited to:

- (1) Evaluating, developing, improving, sustaining, or restoring skills in activities of daily living (ADL), work or productive activities, including instrumental activities of daily living (IADL) and play and leisure activities;
- (2) evaluating, developing, remediating, or restoring sensorimotor, cognitive or psychosocial components of performance;
- (3) designing, fabricating, applying, or training in the use of assistive technology or orthotic devices and training in the use of prosthetic devices;

11-3

(4) adapting environments and processes, including the application of ergonomic principles, to enhance performance and safety in daily life roles;

(5) applying physical agent modalities as an adjunct to or in preparation for engagement in occupations;

(6) evaluating and providing intervention in collaboration with the client, family, caregiver or others;

(7) educating the client, family, caregiver or others in carrying out appropriate nonskilled interventions; and

(8) consulting with groups, programs, organizations or communities to provide population-based services.

(d) "Occupational therapist" means a person licensed to practice occupational therapy as defined in this act.

(e) "Occupational therapy assistant" means a person licensed to assist in the practice of occupational therapy under the supervision of an occupational therapist.

(f) "Person" means any individual, partnership, unincorporated organization or corporation.

(g) "Physician" means a person licensed to practice medicine and surgery.

(h) "Occupational therapy aide," "occupational therapy tech" or "occupational therapy paraprofessional" means a person who provides supportive services to occupational therapists and occupational therapy assistants in accordance with K.S.A. 65-5419, and amendments thereto.

4-11

Sec. 2. K.S.A. 65-28,127 is hereby amended to read as follows: 65-28,127. (a) Every responsible licensee who directs, supervises, orders, refers, accepts responsibility for, enters into practice protocols with, or who delegates acts which constitute the practice of the healing arts to other persons shall:

- (1) Be actively engaged in the practice of the healing arts in Kansas;
- (2) review and keep current any required practice protocols between the responsible licensee and such persons, as may be determined by the board;
- (3) direct, supervise, order, refer, enter into a practice protocol with, or delegate to such persons only those acts and functions which the responsible licensee knows or has reason to believe such person is competent and authorized by law to perform;
- (4) direct, supervise, order, refer, enter into a practice protocol with, or delegate to other persons only those acts and functions which are within the normal and customary specialty, competence and lawful practice of the responsible licensee;
- (5) provide for a qualified, substitute licensee who accepts responsibility for the direction, supervision, delegation and practice protocols with such persons when the responsible licensee is temporarily absent;
- (6) comply with all rules and regulations of the board establishing limits and conditions on the delegation and supervision of services constituting the practice of medicine and surgery.

(b) "Responsible licensee" means a person licensed by the state board of healing arts to practice medicine and surgery or chiropractic who has accepted responsibility for the actions of persons who perform acts pursuant to practice protocols with, or at the order of, or ~~referral~~ direction, supervision or delegation from such responsible licensee.

(c) Except as otherwise provided by rules and regulations of the board implementing this section, the physician assistant licensure act shall govern the direction and supervision of physician assistants by persons licensed by the state board of healing arts to practice medicine and surgery.

(d) Nothing in subsection (a)(4) shall be construed to prohibit a person licensed to practice

medicine and surgery from ordering, authorizing or directing anesthesia care by a registered nurse anesthetist pursuant to K.S.A. 65-1158 and amendments thereto.

(e) Nothing in this section shall be construed to prohibit a person licensed to practice medicine and surgery from ordering, authorizing or directing physical therapy services pursuant to K.S.A. 65-2901 et seq. and amendments thereto.

(f) Nothing in this section shall be construed to prohibit a person licensed to practice medicine and surgery from entering into a co-management relationship with an optometrist pursuant to K.S.A. 65-1501 et seq. and amendments thereto.

(g) The board may adopt rules and regulations establishing limits and conditions on the delegation and supervision of services constituting the practice of medicine and surgery.

(h) This section shall be part of and supplemental to the Kansas healing arts act.