Approved: March 3, 2011
Date

MINUTES OF THE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman Vicki Schmidt at 1:00 p.m. on February 15, 2011, in Room 546-S of the Capitol.

All members were present.

Committee staff present:
Nobuko Folmsbee, Office of the Revisor of Statutes
Melissa Calderwood, Kansas Legislative Research Department
Iraida Orr, Kansas Legislative Research Department
Carolyn Long, Committee Assistant

Conferees appearing before the Committee:
Marjorie Powell, Pharmaceutical Research Manufacturing Association
Darlene Whitlock, Stormont-Vail
Dr. Don Fishman

Others attending:
See attached list.

The Chair opened the hearing on **SB 117—Drug utilization review program; subject to KOMA rules and regulations.** Staff stated that this legislation would require meetings of the Medicaid Drug Utilization Review Board to be held subject to the provisions of the Kansas Open Meetings Act. It would add four (4) requirements for meeting conduct: (1) non-members of the committee could only be recognized to speak during designated public comment periods; (2) manufacturers and other interested parties would have to submit formulary requests in a standard format three or four weeks in advance of the meeting; (3) the KHPA would have to notify interested parties of committee meetings at least six weeks before the meeting date; and, (4) before final action was taken, a 15-minute public comment period would be required for each drug in the therapeutic drug class under review.

Marjorie Powell, legal counsel for the Pharmaceutical Research Manufacturing Association (PhRMA), commends the bill for separating the prescription drug formulary advisory committee from the drug utilization board process; for establishing detailed procedures for the creation of the preferred drug list; establishing a process for input for pharmaceutical manufacturers, providers, patients and other interested parties to provide information to the Committee during a public comment period; and including a specific direction that the committee should consider first and foremost the efficacy and safety of the specific medicines (Attachment #1).

The Chair called upon Dr. Barbara Langner, Medicaid Director, Kansas Health Policy Authority (KHPA), to clarify some of the issues raised by Ms. Powell. She said opposition to this legislation by the KHPA was due to the fact that it lengthened the time for collection of rebates, not as many drugs could be reviewed in any one session, and finally who could talk during the session.

The Chair asked if the Kansas Health Policy Authority would commit to meeting with the Pharmaceutical Research and Manufacturers of America and Dr. Robert Moser from the Department of Health and Environment in order to evaluate their current position and the direction they should take. The KHPA agreed to proceed with PhRMA.

There being no further conferees, the hearing on **SB 117** was closed.

The hearing on **SB 139—Members of regional trauma councils and advisory committee on trauma** was opened. Staff stated that this bill would clarify that members of the Regional Trauma Councils (RTC) and members of the Advisory Council on Trauma (ACT) under the authority of the Kansas Department of Health and Environment are considered peer review officers.

Darlene Whitlock, nurse educator from Stormont-Vail Regional Hospital, informed the committee that as a member of the Kansas Emergency Nurses Association, the Association was in support of this legislation. Emergency nurses from each of the six trauma regions have been actively involved in the development of the Kansas Trauma System to assure quality by evaluating the care delivered, thus benefiting future patients and serving as an educational opportunity for all involved (Attachment #2).

The minutes of the Public Health and Welfare Committee at 1:00 p.m. on February 15, 2011, in Room 546-S of the Capitol.

Dr. Don Fishman, a trauma surgeon from Overland Park, stated that evaluation of statewide trauma system effectiveness, accessibility, cost, and quality of care is essential. Use of identifying records to analyze performance and identify opportunities for improvement is imperative. These records must be accessible for these purposes while being protected from inappropriate disclosure (Attachment #3).

Dr. Rosanne Rutkowski, Kansas Department of Health and Environment (Attachment #4) and Chad Austin, Kansas Hospital Association (Attachment #5) both presented written testimony in favor of this legislation.

There being no further conferees, the hearing on **SB 139** was closed.

The Chair called for final action on **SB 33—school sports head injury prevention.** A technical amendment was introduced to read "Healthcare provider" means a person licensed to practice medicine or surgery, or an advanced registered nurse practitioner, a physician assistant, or an athletic trainer working pursuant to delegation by or a written collaboration agreement with a person licensed to practice medicine or surgery. It was moved by Senator Brungardt, seconded by Senator Huntington to adopt the Chairs' technical amendment to the bill regarding changing advanced registered nurse practitioner to advanced practice registered nurse. Motion carried.

After further discussion by the committee it was moved by Senator, Brungardt, seconded by Senator Huntington to insert the definition "by a person licensed to practice medicine or surgery" in line 31 in place of "a licensed health care provider". Motion carried.

After further discussion it was decided to work on the wording of the balloons and return the corrected wording back to the committee for final action.

The meeting adjourned at 2:30 p.m. The next meeting of the committee is February 16, 2011.

The next meeting is scheduled for February 16, 2011.

The meeting was adjourned at 2:23 p.m.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE GUEST LIST

DATE: Tuesday, February 15, 2011

NAME	REPRESENTING
Marjorie Powell	PhRMA
Bob Williams	Ks. Assoc. Osteopathic Medicine
Barbara Belcher	Merck
Susan Zalenski	J+J
Darin Conklin	Superior Co.
Leigh Keck	Capitol Strategies
Colin Thomasset	ACMHCK
Chad Austin	KHA
Travis Lowe	Little Govt Relations
Melissa Ward	Irin' Law Firm
Nelson Krueger	LEL
Zac Kohl	Federico Cons.
Darlene Whitlock	KEDA

Statement PhRMA

Statement of the Pharmaceutical Research and Manufacturers of America

Senate Bill 117
February 15, 2011

PhRMA represents the leading research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

PhRMA would like to commend the sponsor of Senate Bill 117 for:

- Separate the prescription drug formulary advisory committee (PDL Committee) from the drug utilization board (DUR Board) process; as these represent two distinct processes related to the prescription drugs that physicians will prescribe for Kansas Medicaid patients. However, the coordination of the activities of both the PDL Committee and the DUR Board are critical in keeping the recommendations orderly and transparent. The PDL Committee is charged with advising the Kansas health policy authority on what medicines are likely to be most effective for treating the diseases that afflict the Kansas Medicaid beneficiaries, while the DUR Board is charged with performing prospective and retrospective reviews of drug utilization by physicians treating Medicaid patients; and developing prior authorization criteria for non-preferred drugs and drug categories.

- Establishing detailed procedures for the creation of the preferred drug list, including details about the factors that the preferred drug list advisory committee is to consider when reviewing drugs and the requirement for public notice of the advisory committee meetings.

- Establishing a process for input for pharmaceutical manufacturers, providers, patients and other interested parties to provide information to the PDL Committee during a public comment period before the Committee makes any recommendations about whether to include a drug on the preferred drug list. Physicians and researchers, as well as manufacturers of the drugs being considered by the advisory committee may have new and important information about both safety and effective use of medicines.

- Including a specific direction that the preferred drug list advisory committee should consider first and foremost the efficacy and safety of the specific medicines being reviewed in light of the characteristics of the Medicaid population – patients with multiple chronic conditions. The bill's language about consideration of "net economic impact" is also important, because a less expensive medicine with a side effect that causes patients to stop taking the medicine is less effective in the long term than a more expensive medicine that a patient continues to take.

However, PhRMA would like to offer several suggestions that would further strengthen the work of the preferred drug list advisory committee in considering drugs for the preferred drug list and the DUR Board. PhRMA believes that these suggestions are consistent with best practices in other states, with the Medicaid law and regulations, and offer important safeguards for the health and safety of Kansas residents participating in the Medicaid program.

PhRMA recommends that Senate Bill 117 be amended to:

- Provide at least six weeks notice of a meeting of the preferred drug list advisory committee on the agency's website.

- Provide at least four weeks notice of the classes and specific drugs to be reviewed at the meeting.

- Require that the PDL Committee and DUR Board meet quarterly. This allows the state to more evenly distribute the work load of drugs and drug classes to be reviewed (annually, as well) and contracted per each quarterly meeting, while receiving the most updated clinical practice evidence and safety information available in a timely manner.

- Allow manufacturers to submit to the PDL Committee clinical information that the manufacturer believes would be relevant to the committee's review of the drug. Allow public comment submissions from other interested parties, such as providers and patients.

- Include a provision that a patient who is doing well on a specific drug can continue on that drug if the preferred drug for the patient's disease changes. Essentially, this concept "grandfathers" existing treatments that are already successfully keeping patients healthy. Patients will not have to change medicines because the Medicaid program has made administrative changes.

- Include a requirement that the PDL Committee review all drugs within a specific class, or to treat a specific disease or condition, every year. This ensures that the preferred drug list is based on the most current knowledge of diseases and their treatments.

- Include a requirement that physicians treating Medicaid patients can prescribe a newly approved medicine if the physician believes that it will be more effective for a specific Medicaid patient than the medicine on the preferred drug list. Medicaid patients should have access to new drug therapies during the time before they are reviewed by the advisory committee. Newer medicines may also be associated with a more tolerable side effect profile or less frequent dosing requirements that can improve patient compliance with the prescribed treatment.

- Include a requirement that KHPA provide public notice to all interested parties, including drug manufacturers, about what drugs are preferred and non-preferred within 45 days after the PDL Committee meeting. Direct that the DUR Board consider prior authorization criteria recommendations for any specific drug only after the drug has been reviewed by the PDL Committee and recommended as non-preferred on the PDL by KHPA.

- Include a provision that the chair of the PDL Committee can not serve as the chair or vice chair of the DUR Board. The tasks assigned to the DUR Board may result in that Board recommending that the PDL Committee reconsider one or more recommendations for preferred drugs, based on the Board's review of physicians' actual prescribing practices and efforts to educate physicians. That task is more difficult if a single person is chairing both the Board and the committee.

In addition, PhRMA recommends that the Committee:

- Modify the DUR Board provision in Section 1(c) to conform to the federal requirement that at least one third, but no more than 51 percent of the DUR Board members be licensed, practicing physicians, not "any class of professional representatives" as set forth on line 33 of page 1.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines. PhRMA members alone invested an estimated $45.8 billion in 2009 in discovering and developing new medicines. Industry-wide research and investment reached a record $65.3 billion in 2009.

Session of 2011

SENATE BILL No. 117

By Committee on Ways and Means 2-7

Proposed PhRMA amendments to SB 117

Page 1 starting on line 32 insert

32 (c) The Kansas health policy authority may add two additional members so long as no class of professional representatives exceeds 51% of the membership and physicians are between 30 and 51% of the membership.

Page 2 starting on line 6 insert

6 (f) The board shall elect a chairperson from among board members who ~~shall serve a one-year term. The chairperson may serve consecutive terms~~ does not serve as a chairperson or vice chairperson in any other Medicaid advisory committee capacity. The chair person may serve four one-year term.

Page 3 starting on line 39

39 (b) The Kansas health policy authority shall evaluate drugs and drug classes for inclusion in the state medicaid preferred drug formulary based on safety, effectiveness and clinical outcomes of such treatments. ~~In addition, the Kansas health policy authority shall evaluate drugs and drug classes to determine whether inclusion of such drugs or drug classes in a starter dose program would be clinically efficacious and cost effective.~~

Page 4 starting on line 35 add two subsections under section (f)

(1) The Kansas health policy authority and any advisory committee established pursuant to subsection (a), including the preferred drug list committee, shall notify all pharmaceutical manufacturers and other interested parties known to the agency and the advisory committee of meeting dates at least six weeks in advance of such meeting date. Agenda items shall be posted four weeks prior to the meeting. The agenda shall list the therapeutic drug classes and the specific drugs within each class to be reviewed. The preferred drug list committee shall meet at least quarterly in a calendar year.

(2) All Therapeutic drug classes shall be reviewed annually during one of the four preferred drug list committee meetings.

Page 4 starting on line 39

~~*(1) Nonmembers of the committee and other interested parties shall be recognized by the comittee chairperson only during designated public comments periods.*~~

(2) Pharmaceutical manufacturers or other interested parties shall submit ~~their formulary submission in a standardized format~~ comments, information about drug safety, effectiveness and clinical outcomes to the Kansas health policy designee at least three to four weeks prior to the date of the meeting of the advisory committee established pursuant to subsection (a), including the preferred drug list committee. The preferred drug list advisory committee shall take into consideration the comments and materials provided by pharmaceutical manufacturers and other interested parties prior to making any decisions about drugs.

~~*The Kansas health policy authority and any advisory committee established pursuant to subsection (a), including preferred drug list committee, shall notify all pharmaceutical manufacturers or other interested parties known to the agency and the advisory committee of such meeting date at least six weeks in advance of such meeting date.*~~

Page 5 starting on line 16

(4) The Kansas health policy authority shall notify manufacturers and other interested parties of the preferred and non-preferred status of drugs for the preferred drug list within 45 days after the meeting of the preferred drug advisory committee meeting and before the Drug Utilization Review Committee meeting to review such drugs to establish prior authorization criteria. This notification shall be posted on the Kansas health policy website.

Testimony on SB 139
Presented to
Senate Public Health and Welfare Committee

By Darlene S. Whitlock RN, ARNP
Immediate Past President, Kansas Emergency Nurses Association

February 15, 2011

Chairman Schmidt and members of the Senate Public Health and Welfare Committee, the Kansas Emergency Nurses Association would like to provide testimony in support of SB 139.

Emergency nurses from each of the six trauma regions have been actively involved in the development of the Kansas Trauma System through Regional Trauma Councils and the Advisory Committee on Trauma. One of the many components of a trauma system is to assure quality by evaluating the care delivered.

As individual trauma centers have developed across the state, they have evaluated the care delivered through a performance improvement process. As the state system has matured, the need for regional and statewide process improvement has evolved. An impediment to this progression has been the lack of peer protection status. Senate Bill 139 will help ensure that the rigorous evaluation of trauma care will occur, yet be protected. This will translate into improved outcomes and lives saved.

Although providers strive to give the best care possible, close scrutiny of events, in a non-threatening setting, often yields opportunities to improve. This type of evaluation can only benefit future patients and serve as an educational opportunity for all involved.

Thank you for the opportunity to express our support of SB 139.

KANSAS TRAUMA PROGRAM PLAN NOW. SAVE LIVES.

Chairman Schmidt and Members of the Committee, I am Dr. Don Fishman. I am a trauma surgeon with a practice in Overland Park but am here today representing the Advisory Committee on Trauma. The Advisory Committee on Trauma would like your support on SB 139.

Last year, over 1,300 Kansans died from unintentional injuries suffered on the road, the farm, or in the home. We also know each day there are 25 Kansans injured severally enough to require the services of a trauma center. Injuries are a leading causing of death for Kansans 1-44 years old and are life altering events for the elderly.

In 1999, the Kansas legislature recognized that injuries were a significant public health issue in Kansas and established the Kansas Trauma Program. The Secretary of Health and Environment was directed to develop and implement a statewide trauma system, including a Kansas Trauma System plan, to include system components such as trauma center designation, regional trauma councils, quality improvement programs, and a statewide trauma data collection system. The legislation established an Advisory Committee on Trauma (ACT) to provide input to KDHE on the development of the statewide trauma system.

Development of a trauma system is based on the idea that injury outcomes improve by instituting standards to ensure the timely transfer of injured patients to hospitals with resources matched to the needs of the patient. Research supports the premise that hospital mortality from trauma is reduced significantly with the implementation of a trauma system.

The purpose of the Kansas Trauma System is to assure a comprehensive trauma system which provides high quality trauma care resulting in the best possible patient outcomes. A continuous, comprehensive, multi-disciplinary, evidence-based, performance improvement process promotes monitoring and evaluation of the trauma system. It provides identification of opportunities for improvement and development of strategies for correction.

Evaluation of statewide trauma system effectiveness, accessibility, cost, and quality of care is essential. It is the role of the state trauma program to assure consistency in the strategies used for process improvement statewide, and to monitor, analyze and report improvement in the system along with deficiencies needing to be addressed. However, a statutory barrier exists to the use of the system data for quality management and performance improvement. While the regional trauma plans already contain recommendations for quality improvement processes, use of the trauma registry data for quality improvement process is not occurring at this time because existing statute does not include peer review protections in the use of this data. We need to use identifying records to analyze performance and identify opportunities for improvement. These records must be accessible for these purposes, while being protected from inappropriate disclosure. The contents of this bill will accomplish this purpose.

We ask that you support SB 139. I'll be happy to answer any additional questions you might have.

Senate Public Health & Welfare
Date 2-15-2011
Attachment 3

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Robert Moser, MD, Acting Secretary

Department of Health & Environment

Sam Brownback, Governor

Written Testimony on SB 139

Presented to
Senate Public Health and Welfare Committee

By
Rosanne Rutkowski, RN, MPH
Director, Kansas Trauma Program
Kansas Department of Health and Environment

February 15, 2011

Chair Schmidt and members of the committee, the Kansas Department of Health and Environment would like to provide written testimony in support of SB 139.

State trauma systems have been developed on evidence-based research that suggests injury outcomes improve when standards of care are instituted to ensure optimal care of the trauma patient.

Legislation was passed in 1999 authorizing the development and implementation of a statewide trauma system in Kansas. KDHE, with input from the Advisory Committee on Trauma (ACT), has successfully developed and implemented the key components of a comprehensive trauma system, including: 1) establishment of regional councils; 2) implementation of a statewide data collection system and quarterly data reports; 3) support for training and education of Kansas health care providers on trauma care; and 4) support of injury prevention activities that is driven by data.

Kansas has six robust regional trauma councils that implement activities to develop regional care systems. The activities of these councils support: 1) reducing the number of injuries; 2) improving the outcomes of those who are injured; and 3) facilitating appropriate use of health care resources. Setting up an organized regional care system is important, because severe trauma is a time-sensitive condition that can be immediately life-threatening. Very often access to specialized care is needed for special populations, e.g., pediatrics and geriatrics, which requires an organized regional and state system for accurate and rapid assessment and transfer. Inter-facility and inter-disciplinary peer review is an essential component in developing these trauma care systems. The ability to implement in a peer review process would allow the regional trauma councils and the ACT is to assess and address important regional and state issues that affect trauma care and outcomes.

Currently, peer review protection for this kind of regional and state-level quality improvement is not explicitly provided for under current Kansas law. SB 139 provides the needed protections for the ACT and the regional trauma councils to implement a peer review process that will allow trauma care providers to share their experiences for the purposes of accountability, mutual learning and identification of opportunities for system improvement. KDHE supports SB 139.

Thank you for the opportunity to provide these written comments.

Senate Public Health and Welfare
Date 2-15-2011
Attachment 4

Tom Bell
President and CEO

TO: Senate Public Health and Welfare Committee

FROM: Chad Austin
Vice President, Government Relations

DATE: February 15, 2011

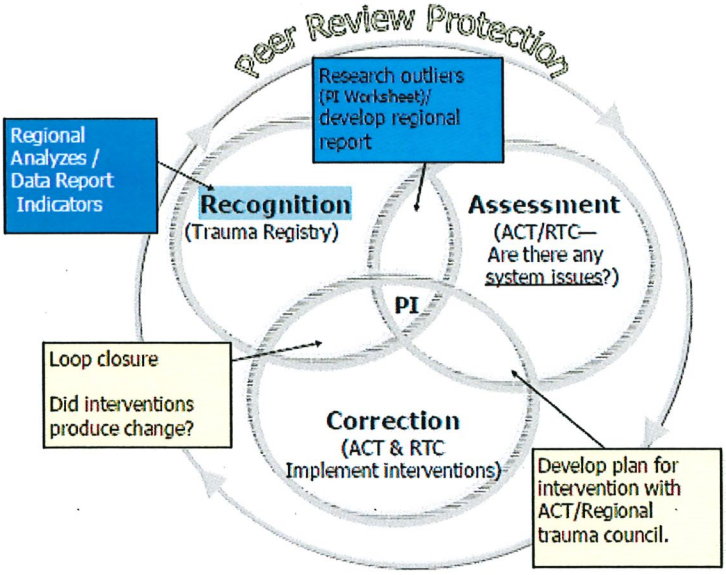
SUBJECT: Senate Bill 139

The Kansas Hospital Association appreciates the opportunity to testify in support of Senate Bill 139 as it allows regional trauma councils and the advisory committee on trauma to engage in peer review. By clearly defining the advisory committee on trauma and regional trauma councils as "health care providers", it affords them peer review protection under Kansas Statute (K.S.A. 65-4915). The regional peer review process will ensure that the most appropriate care is rendered to a patient. This activity will further integrate rural and metropolitan hospitals across the state by encouraging process improvement for trauma. As hospitals work in collaboration with state efforts to develop a coordinated and effective trauma system, the peer review process plays a key part in monitoring quality. The development of a statewide trauma system of care includes a mechanism for ongoing evaluation to improve the process and effectiveness of the system as a whole and by its components – pre-hospital, dispatch, medical control, field triage, hospital care, inter-facility triage, and rehabilitation care.

A performance improvement plan in an organized trauma care system consists of internal and external monitoring and evaluation of care provided through the phases of care and continuum of care. The goal of monitoring is to identify opportunities to reduce inappropriate variations in care and to develop corrective action strategies. The effectiveness of the corrective action is monitored and measured through progressive review cycles. A multidisciplinary trauma peer review process demonstrates appropriate discussion of the identified performance improvement issue, impact on patient care, standard of care review, and action plan. The attached diagram illustrates the regional trauma performance improvement process envisioned by Kansas.

On behalf of the Kansas Hospital Association, I urge your support of Senate Bill 139. Thank you for your consideration of our comments.

Regional PI


peer Review Protection
Research outliers (PI Worksheet)/ develop regional report
Regional Analyzes / Data Report Indicators
Recognition
(Trauma Registry)
Assessment
(ACT/RTC— Are there any system issues?)
PI
Loop closure
Did interventions produce change?
Correction
(ACT & RTC Implement interventions)
Develop plan for intervention with ACT/Regional trauma council.