Approved: 3-11-08
Date

MINUTES OF THE SENATE FINANCIAL INSTITUTIONS AND INSURANCE COMMITTEE

The meeting was called to order by Chairman Ruth Teichman at 9:30 A.M. on February 26, 2008 in Room 136-N of the Capitol.

All members were present.

Committee staff present:
Melissa Calderwood, Kansas Legislative Research Department
Ken Wilke, Office of Revisor of Statutes
Bev Beam, Committee Secretary
Jill Shelley, Kansas Legislative Research Department

Conferees appearing before the committee:
Senator Barbara Allen
Dr. Roy Jensen, Director, KU Cancer Center
Jerry Slaughter, Kansas Medical Society
Lisa Benlon, American Cancer Society
Tom Bell, President, KHA
Dr. Marcie Nielson, HPA
Sandy Praeger, Insurance Com. (Written only)
Larrie Ann Lower, Kansas Assn. Of Health Plans
Bill Sneed, Counsel, America's Health Insurance Plan

Others attending:
See attached list.

The Chair opened the meeting.

Hearing on:

SB 629 - concerning insurance; relating to coverage for patient care services in a cancer clinical trial

Senator Barbara Allen testified in support of SB 629. Senator Allen stated that SB 629 will simply assure Kansans their health plan will pay for the costs of routine patient care services when they are accepted into a bona fide cancer clinical trial, if those same routine patient care services are covered off clinical trial. She stated that routine patient care services are the usual costs of medical care, such as doctor visits, hospital stays, clinical laboratory tests, x-rays and other routine services one would receive whether or not he/she was participating in a clinical trial. She said some health plans don't cover these costs once a patient joins a clinical trial, even though studies have shown these costs are not appreciably higher than costs for patients who are not enrolled in clinical trials. (Attachment 1)

Dr. Roy A. Jensen, Director, University of Kansas Cancer Center, testified in support of SB 629. Dr. Jensen stated that SB 629 does not implement a wide-sweeping change in policy coverage, nor does it implement an undue burden onto insurance companies. Rather, it merely changes a technicality that ensures care that is already being covered, not be discontinued as a result of enrollment in a clinical trial. He said most insurance policies in the state of Kansas cover routine care for patients on clinical trials. He said this would impact at most 5% of patients. Dr. Jensen noted that twenty-three states currently require routine care coverage for patients who participate in a clinical trial. Of those twenty-three states, 53% of NCI's Cancer Centers are located in those states. Dr. Jensen said SB 629 not only furthers the field of cancer research, but it moves us closer to the ultimate goal of eliminating cancer for good by ensuring everyone has access to the latest advancements. (Attachment 2)

Jerry Slaughter, Executive Director, Kansas Medical Society, also testified in support of SB 629. Mr. Slaughter said SB 629 makes it clear that insurers must pay for routine patient care services when a patient is accepted into a bona fide cancer clinical research trial, if those same services are otherwise covered off-trial. Mr. Slaughter said because not all insurers do provide continuity of coverage, this legislation makes it clear that it is the policy of this state to do so. (Attachment 3)

Lisa Benlon, Legislative/Government Relations Director for the American Cancer Society, testified in support of SB 629. Ms. Benlon stated that there have been great successes in finding medical breakthroughs for cancer using clinical trials. She noted that the breakthroughs are sometimes slow in coming due to insurance companies failing to be a partner in the health care of those they insure. She said the American Cancer Society believes whether or not a clinical trial is taking place, the insurance company should be covering the same procedures. (Attachment 4)

Tom Bell, President, Kansas Hospital Association, testified in support of SB 629. Mr. Bell stated that this legislation clarifies that insurers are required to pay for routine patient care services in a clinical cancer research trial, if those same services would otherwise be covered. Mr. Bell noted that a growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care received as a participant in a clinical trial. Lack of such coverage is a significant barrier to many patients who might otherwise enroll in a trial, he said. He continued that lack of coverage also makes it harder for researchers to successfully conduct trials that could improve prevention and treatment options. (Attachment 5)

Dr. Marcie Nielson, Kansas Health Policy Authority, testified as neutral on SB 629. She stated that clinical trials offer patients access to new and potentially life saving drugs and cures. She said participation in clinical trials is low – only two to three percent of eligible adult patients enroll in clinical trials with health insurance coverage of routine care being a barrier. She noted that Kansas Health Policy Authority covers the cost of routine care for patients enrolled in a clinical trial in both the State Employee Health Plan and in Medicaid. She noted that for cancer patients, clinical trials are often the last resort after exhausting all other approved means of treatment. (Attachment 6)

Sandy Praeger, Commissioner of Insurance, submitted neutral written testimony regarding SB 629. (Attachment 7)

Larrie Ann Lower, representing Kansas Association of Health Plans, submitted neutral written testimony in opposition to SB 629. (Attachment 8)

William W. Sneed, Legislative Counsel for America's Health Insurance Plans, testified in opposition to SB 629, stating that notwithstanding the good intentions behind the introduction of SB 629, we believe its enactment is unnecessary and, in certain instances, may hamper the utilization of clinical trials. We would contend that this mandate is unnecessary for the following reasons: (1) Health plans already provide appropriate access to clinical trials, making mandating legislation unnecessary; (2) Because clinical trials evaluate the safety and efficacy of new therapies, it is critical that trials be designed in ways that maximize patient safety; (3) A legislative mandate to cover clinical trials is likely to increase the cost of health coverage, given that there are numerous procedures, tests and laboratory work that are performed more frequently in the context of the trial than under standard therapy; (4) A legislative mandate imposes a "one size fits all" approach to covering clinical trials when, in fact, all trials are not created equally. (Attachment 9)

The Chair closed the hearing on SB 629 .

Final Action

SB 560 - An act establishing the property/casualty flex-rating regulatory improvement act; pertaining to personal lines insurance written on risks in this state by any insurer authorized to do business in this state.

The Chair briefly explained the bill and asked Ken Wilke for his input. Mr. Wilke said the amendments to SB 560 were proffered by the Insurance Department. He said the Insurance Department was requesting changing the 12% down to 7% so the band on the limitation is much smaller. They also wanted to include on line 17 a 25% cap on individual insureds, he said. On Page 2, line 16, they wish to change the term "means" to "includes." Apparently they feel there are other provisions of the insurance code that need to be picked up insofar as unfairly discriminatory rates are concerned. There are provisions where rates are considered unfairly discriminatory and not on the basis of race, color, creed, or national origin. Exactly what

all the Insurance Department wishes to pick up here, I am not sure. Mr. Wilke said it is his recollection that the bill as presented initially was the recommendation of the Task Force.

Bill Sneed said he supports the bill as written. He noted that's what the task force came up with. He said we believe it to be a compromise, so we urge your support.

The Chair said that because the task force agreed on the language in this bill, she recommended the bill be amended only on page 2, changing the word in line 16 (b) from "means" to "includes."

Senator Schmidt moved to amend SB 560 on page 2 only. Senator Steineger seconded. Motion passed.

Senators Brownlee, Barone and Wilson abstained.

Senator Wysong moved to pass SB 560 out favorably as amended. Senator Brungardt seconded. Motion passed.

Senator Steineger moved the F I & I Committee Minutes of February 6, 12, 13, and 14 be approved as written. Senator Wilson seconded. Motion passed.

SENATE FINANCIAL INSTITUTIONS & INS. COMMITTEE
GUEST LIST

DATE: 2-26-08

NAME	REPRESENTING
Janet Neff	KDHE Cancer Program
Alex Kotoyantz	P.I.A.
Laura Jones	UHG
John Meek	KID
Bill Sneed	AHIP
LARRY MAGILL	KAIA
KERRI SPIELMAN	KAIA
Michelle Peterson	Capitol Strategies
	KUCC

STATE OF KANSAS

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COMMITTEE ASSIGNMENTS
CHAIR: ASSESSMENT AND TAXATION
MEMBER: EDUCATION
JUDICIARY

TOPEKA
SENATE CHAMBER

Senate Financial Institutions & Insurance Committee

Tuesday, February 26th, 2008

RE: SB 629 – Coverage of "Routine Patient Care Services" in Cancer Clinical Trials

Madame Chair:

Thank you for the opportunity to testify today on **SB 629**, which concerns coverage of routine patient care services when a patient enrolls in a cancer clinical trial in Kansas.

I am working with Dr. Roy Jensen, Director of the University of Kansas Cancer Center (KUCC), whom you will hear from shortly. SB 629 will simply assure Kansans their health plan will pay for the costs of routine patient care services when they are accepted into a bona fide cancer clinical trial, if those same routine patient care services are covered off trial.

Routine Patient Care Services. These "routine patient care services" are the usual costs of medical care, such as doctor visits, hospital stays, clinical laboratory tests, x-rays and other routine services one would receive whether or not he/she was participating in a clinical trial. Some health plans don't cover these costs once a patient joins a clinical trial, even though studies have shown these costs are not appreciably higher than costs for patients who are not enrolled in clinical trials.

What Costs Would Continue To Be The Responsibility of the Sponsor of the Clinical Trial Under SB 629? The costs directly related to the clinical trial would continue to be the responsibility of the sponsoring organization (i.e. the pharmaceutical company) under SB 629. In other words, the health plan would not be asked to cover the direct costs associated with a clinical trial, but rather only the routine patient care costs that would otherwise be covered if the patient was not enrolled in a clinical trial.

Do we really need to pass SB 629 this year? The University of Kansas Cancer Center (KUCC) will be submitting its application to become a National Cancer Institute (NCI)-Designated Cancer Center in 2010. One of the factors under consideration in granting NCI designation to KUCC is its accrual number, or patients enrolled in cancer clinical trials. Any barriers to placing patients on cancer clinical trials in Kansas will be viewed negatively by the NCI.

FI & I Committee
February 26, 2008
Attachment 1

Isn't This Just A Small Problem Anyway? It's true that for the most part, Kansas health plans already cover routine health care services when a patient enrolls in a cancer clinical trial. We estimate only 5% of all patients who want to enroll in a clinical trial will be affected by this bill. But if you, your wife, mother, sister, or daughter is the one who is denied coverage of routine health care services on a clinical trial, it is a very big deal!

The Key To the Cure Is In Research. The whole purpose of clinical trials is to conduct research that will lead to finding answers and eventually a cure for all cancers. Cancer clinical trials are not just about curing a particular patient, but rather, about conducting research for the greater good, to find a cure for all patients who develop a particular type of cancer. In the long run SB 629 will save health plans money, because with research comes answers to what types of drugs actually work, rather than requiring coverage for drugs that are ultimately discovered to have no effect on a particular type of cancer.

Isn't this a Mandate That Will Raise Costs of Health Care for Everyone? While health plans will try to paint SB 629 as a mandate, the reality is these routine patient care services are already provided to most cancer patients by Kansas health plans. SB 629 is really just a clarification of current law. These routine patient care services are already covered if the patient is not enrolled on a clinical trial. It is only when a patient enrolls on a cancer clinical trial that a health plan in rare instances withdraws all coverage for the patient, including routine care. In this instance, the patient decides not to enroll on the trial and continues to receive coverage for the routine care outside of a clinical trial setting. This is why studies show this legislation has little or no impact on costs to the health plans.

Does the State Health Plan Pay for Routine Patient Care Costs? The state of Kansas continues to cover the cost of routine health care services for plan participants when an employee is accepted into a clinical trial. Parallel to the provisions of SB 629, "the state does not pay for the direct costs associated with a clinical trial but does cover routine health care costs which would otherwise be covered under the employees benefit plan when accepted into a clinical trial." (e-mail from Reagan Cussimanio, KHPA, 1-29-08).

World Class Health Care in Kansas. Cutting-edge clinical trials are critical because they provide patients access to world class health care and physician/scientists with research that leads to cures for cancer. Cancer patients in Kansas deserve access to world class health care right here at home with their family and friends to support them. This bill removes a barrier, although small, to patients enrolling in cancer clinical trials. As an institution that will be very heavily involved in Phase I trials, passage of SB 629 is crucial to KUCC's overall goal of achieving NCI designation as a Comprehensive Cancer Center.

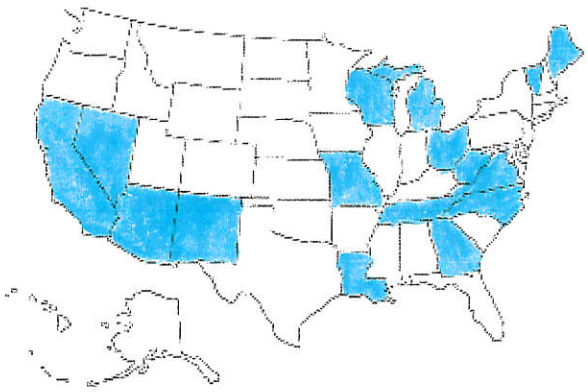
Madame Chair, thank you for your consideration. I will be happy to stand for questions at the appropriate time.

Attachments: NCI map - States That Require Health Plans to Cover Patient Care Costs in Clinical Trials; Memo from Kansas Health Policy Authority (KHPA), 1-24-08

Barbara P. Allen

Posted: 12/19/2002 **Updated:**

States That Require Health Plans to Cover Patient Care Costs in Clinical Trials



A growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care you receive as a participant in a clinical trial.

Use this map to link to an overview of each state's law or agreement and its key provisions.

"Routine patient care costs" are the usual costs of medical care, such as doctor visits, hospital stays, clinical laboratory tests, x-rays, etc., that you would receive whether or not you were participating in a clinical trial. Some health plans don't cover these costs once you join a trial, even though studies have shown that they are not appreciably higher than costs for patients who are not enrolled in trials. (See Cost of Clinical Trials [1].)

Lack of such coverage is a significant barrier to many patients who might otherwise enroll in a trial. Lack of coverage also makes it harder for researchers to successfully conduct trials that could improve prevention and treatment options.

These laws and agreements do not cover the research costs associated with the conduct of the trial, such as tests purely performed for research purposes. In most cases, such costs would be paid for by the group sponsoring the trial, such as the National Cancer Institute or a pharmaceutical company.

For more of an overview, see Clinical Trials and Insurance Coverage: A Resource Guide. [2]

To find specific trials in PDQ -- the National Cancer Institute's database of ongoing cancer clinical trials -- go to the PDQ search page. [3]

To understand the basics of clinical trials, please see the variety of articles listed in the Educational Materials About Clinical Trials [4] section of this Web site. Of particular interest might be What is a Clinical Trial? [5]

Another resource is NCI's State Cancer Legislative Database Program [6].

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KANSAS HEALTH POLICY AUTHORITY

To: Senator Barbara Allen

From: Reagan Cussimanio

Date: January 24, 2008

Subject: Clinical Trials Legislation - Insurance Coverage for "Routine Care"

Senator Allen,

In response to your questions, I have compiled the following information. Please do not hesitate to contact me should you have further questions or concerns.

Does the state of Kansas continue to cover the cost of routine health care services when an employee is accepted into a clinical trial?

Yes, the health plan will continue to cover the cost of routine health care services that are a benefit under their contract. Clinical trials are generally excluded from coverage, but there are exceptions. If the person was approved for coverage of the clinical trial under one of our plans' exceptions, we would also pay for any services related to the cost of the clinical trail. Covered trials are referred to as "research urgent care" in contract terminology, and consist of treatment of life threatening or severely and chronically disabling conditions with a high probability of causing premature death when all other conventional treatments have failed. The treatment has to be clinically significant and show substantial improvement in net health outcome compared to the most effective conventional treatment. Coverage is not available for drugs and biologicals that are available under the prescription drug program.

If so, what has been the experience of the state from a cost standpoint?

We are not able to identify this information. The routine services pay under the codes that they were submitted. These expenses would be lumped together with all other routine services with like codes.

If not, why doesn't the state cover these costs for their employees who are participants in bona fide clinical trials?

The State health plan currently provides cover for routine costs of health care for plan participants involved in clinical trials, whether or not the costs of the trial itself are covered by the plan.

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Phone: 785-296-3981
Fax: 785-296-4813

State Employee Health
Benefits and Plan Purchasing:
Phone: 785-368-6361
Fax: 785-368-7180

State Self Insurance Fund:
Phone: 785-296-2364
Fax: 785-296-6995

MORE SPACE FOR KU MED RESEARCH

KCS 2-21-08

The Hall foundation is buying a Fairway building for center's clinical trials.

By JASON GERTZEN
The Kansas City Star

University of Kansas Medical Center leaders aim to expand the region's pursuit of new drugs and enhanced patient care with a clinic and research center in Fairway.

The **Hall Family Foundation** is buying an office complex that would be provided to the university should voters approve a **Johnson County Education Research Triangle** sales-tax initiative later this year.

"We have a tremendous capability in this community in the drug development field," said Bill Hall, president of the foundation. "What has been done by KU over the years is extraordinary. The ability to combine clinical trials with drug development capabilities should give us a significant leg up."

The Hall foundation is expected to complete the purchase of office buildings in the Fairway Office Park near Shawnee Mission Parkway and Roe Boulevard within the next 30 days. One of the two buildings would go to the university project and another would be maintained as an investment for the foundation, which is the philanthropic arm of the

> "It says to the voters that this is a real proposal."
>
> BILL HALL, PRESIDENT OF THE HALL FAMILY FOUNDATION

SEE HALL | C6

HALL: Plan is to be ready if sales tax passes

FROM C1

founding family of **Hallmark Cards**.

This action comes as a key piece of an effort to strengthen university research and education programs in Johnson County.

County officials will be asked to place a measure on the November ballot seeking voter approval for a ⅛th-cent sales tax expected to generate about $15 million a year.

The money would be divided among the KU Medical Center, the **University of Kansas Edwards Campus** and **Kansas State University**.

The universities would use the money for construction of new facilities in the area, expand degree programs in math and science and to develop new cancer treatments.

After factoring in the value of the college graduates that will emerge from the programs and the additional research activity, organizers of the triangle initiative anticipate it will produce an economic impact of more than $1 billion over 20 years.

K-State is establishing a Kansas City area presence with a project in Olathe. The university is opening a new food security and research institute on a campus that also will be home to the **Kansas Bioscience Authority** and private-sector companies such as **Fort Dodge Animal Health**.

Officials at the KU Edwards Campus intend to move ahead with an effort to create a Business, Engineering & Technology Center focused on providing undergraduate and advanced degree programs in areas such as molecular bioscience and engineering.

The medical center's project would require about $15 million in construction and equipment, which would be provided by the Hall foundation. Having the facility ready to go would provide a jump-start if voters approve the sales-tax proposal, Hall said.

The property for the Edwards and K-State projects is in place, Hall said. It is important to position the medical center in a similar way, he said.

"It says to the voters that this is a real proposal," Hall said.

The 70,000-square-foot facility would help the center advance its quest for recognition as one of the nation's top centers for cancer care and research, said David Adkins, vice chancellor for external affairs for the medical center.

It would provide a home for the headquarters of the **Midwest Cancer Alliance**, a center for clinical trials and research laboratories and the headquarters of a new translational research venture.

The medical center has opened the **Kansas Life Sciences Innovation Center**, 200,000 square feet of offices and labs that has helped recruit top scientists.

The Fairway facility is needed for other programs, the clinical trials research in particular, Adkins said.

"At this point there is not the kind of space on our campus that would be easily and conveniently accessible to patients seeking clinical trials," Adkins said.

Clinical trials require intensive record keeping and supervision by physicians, nurses, data managers and others with specialized expertise, said Roy Jensen, director of the **KU Cancer Center**. Centralizing these efforts at a single facility could improve efficiency and lower costs, Jensen said.

If the cancer center could put more patients on clinical trials at a lower cost, pharmaceutical companies and others developing drugs are likely to favor the center when testing new treatments, Jensen said.

Within a couple of years, Kansas officials will present the growth and success of their cancer initiatives in a bid for recognition as one of the country's top programs by the **National Cancer Institute**. The new clinical trials facility could be an important part of that application, Jensen said.

"If we have this ballot initiative passed and we have a building that is being renovated or is close to being opened, clearly we are demonstrating a visionary approach and that we are putting the plan into action," Jensen said. "That would be a powerful statement."

To reach Jason Gertzen, call 816-234-4899 or send e-mail to jgertzen@kcstar.com.

Testimony Before the Senate Committee on Financial Institutions and Insurance
9:30 am, Tuesday, February 26, 2008
136 North, Kansas State Capitol

Testimony in Support of SB 629
by Roy A. Jensen, MD
Director, University of Kansas Cancer Center

Madam Chair and Members of the Committee:

I am pleased to appear before you today and provide testimony in support of SB 629, legislation that would require routine care coverage for patients participating in clinical trials. I am appearing here today as the director of the University of Kansas Cancer Center and on behalf of my colleagues, including Gary Doolittle, our medical director of the Midwest Cancer Alliance.

SB 629 does not implement a wide-sweeping change in policy coverage, nor does it implement an undue burden onto insurance companies. Rather it merely changes a technicality that ensures care that is already being covered, not be discontinued as a result of enrollment in a clinical trial. Most insurance policies in the state of Kansas cover routine care for patients on clinical trials. We estimate this would impact at most 5% of patients. However some do not provide coverage for routine care, and for those patients this could mean life or death.

Twenty-three states currently require routine care coverage for patients who participate in a clinical trial. Of those twenty-three states, 53% of NCI's Cancer Centers are located in those states.

It is our goal at the KU Cancer Center to eliminate deaths from cancer in our state. As most of you know we are building a world-class cancer center in order to achieve the National Cancer Institute's designation as a Comprehensive Cancer Center. By bringing a world-class Cancer Center to this region, we will be able to offer the most cutting-edge therapeutics to people across the state, giving them access to the latest and best options in fighting their cancer. As a Cancer Center, we develop novel therapies for patients, we treat and diagnosis, but we can't remove all barriers for patients who want to participate in clinical trials. SB 629 has the ability to do this and goes hand in hand in fulfilling our mission at the KU Cancer Center.

We are working hard to build a strong, robust program that flourishes in cancer research and translates discoveries into new therapies for patients through clinical trials. As part of the requirements set forth by the NCI, a cancer center must accrue at a minimum, 10% of patients onto clinical trials in order to have their application considered for Cancer Center designation. By enacting SB 629, the barrier of denied coverage for participation in clinical trials will be

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Attachment 2

removed and more patients will be able and willing to participate, thus ensuring there are no barriers in our efforts towards achieving NCI designation.

Most of you know, we recently launched the Midwest Cancer Alliance. This alliance serves as the outreach arm of the KU Cancer Center, allowing us to push cutting-edge clinical trials out into the state so that patients do not have to travel far to receive their care. Our five founding partner members: Goodland Regional Medical Center, Hutchinson Hospital, Mt. Carmel Regional Medical Center and Stormont-Vail HealthCare will be able to offer this important benefit in each of their communities. We have already removed the barrier of access to clinical trials through the creation of this alliance. SB 629 would complement our efforts with the Midwest Cancer Alliance and allow us to help even more people throughout the state who believe they cannot participate for fear of denied coverage.

SB 629 not only furthers the field of cancer research, but it moves us closer to our ultimate goal of eliminating this disease for good by ensuring everyone has access to the latest advancements.

I would like to end my testimony by telling you about a patient under the care of one of our Cancer Center clinicians, Dr. Stephen Williamson. The patient is a resident of Overland Park and had advanced head and neck cancer. He wanted to participate in a multi-center randomized clinical trial at our cancer center that involves comparing two different types of standard of care for advanced head and neck cancer. The patient contacted his insurance company and was denied coverage. Dr. Williamson called to appeal stating both "arms" of this trial where standard of care for head and neck cancer and should be covered. He provided articles and information from the FDA on the approval of one of the drugs that was being used in the trial. The patient's appeal was denied and he did not get to participate in the clinical trial.

There are many more cases like this where a patient learns about a clinical trial only to be denied coverage. They choose not to go on it, even though it might have prolonged their life or answered an important question on how we treat that particular type of cancer.

Now is the time to put the lives of residents of Kansas first by passing this legislation and removing a significant barrier to participation in clinical trials. Do this because we can reduce the number of deaths from cancer and save lives. But more importantly, it is the right thing to do.

I would like to thank you for this opportunity to testify today. I would be happy to respond to any questions you may have.

Respectfully submitted,

Roy A. Jensen, MD

KANSAS MEDICAL SOCIETY
KMS

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To: Senate Committee on Financial Institutions and Insurance

From: Jerry Slaughter
Executive Director

Date: February 26, 2008

Subject: SB 629; Concerning certain insurance coverage in cancer clinical trials

The Kansas Medical Society appreciates the opportunity to appear in support of SB 629, which makes it clear that insurers must pay for routine patient care services when a patient is accepted into a bona fide cancer clinical research trial, if those same services are otherwise covered off-trial.

It is our understanding that most insurers, as well as the State Employee Health Plan, already provide such coverage. However, to the extent that not all insurers do provide such continuity of coverage, this legislation makes it clear that it is the policy of this state to do so. Our belief is that a patient should not lose coverage for general health care needs, simply because that person is accepted into a cancer clinical trial. Obviously, the sponsoring organization of the clinical trial would be responsible for any direct health care costs associated with the clinical trial itself, and the health insurer would not be responsible for those costs.

We hope that the instances of patients losing coverage for routine health care after they are enrolled in a clinical trial are rare in our state. This legislation simply clarifies this area, and removes any barriers to patients being willing to enroll in a clinical trial. Additionally, given that the University of Kansas Cancer Center is applying to become a National Cancer Institute Designated Cancer Center, this legislation helps send a positive message about our state's commitment to creating an environment that supports cancer research.

We urge you to report SB 629 favorably. Thank you for the opportunity to offer these comments.

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February 26, 2008
Attachment 3

Testimony in favor of SB629
Senate Financial Institutions and Insurance
February 26, 2008

Chairman Teichman and Committee Members:

My name is Lisa Benlon, the Legislative/Government Relations Director for the American Cancer Society. We stand before you today in strong support of SB 629.

There have been great successes in finding medical breakthroughs for cancer using clinical trials. Unfortunately, the breakthroughs are sometimes slower in coming due to insurance companies failing to be a partner in the health care of those they insure.

We hear from our clientele a couple of concerns. First, some contend their physicians do not participate in clinical trials because of the additional personnel it takes to fill out the paperwork needed for the trials and insurance companies. And the second reason is that some insurance companies fail to cover the "customary" procedures if a clinical trial is used.

We believe whether or not a clinical trial is taking place, the insurance company should be covering the same procedures.

We are not asking insurance companies to pay for the actual treatment being tested. It is expected that the cancer program conducting the trial pay for those costs. We just ask that insurance companies pay for the same patient care services whether or not a clinical trial is taking place.

With the help of the insurance companies, we can encourage more physicians to participate if they know this will not be a problem for their personnel and their patients.

With more physicians partnering in the trials, more lives will ultimately be saved from this devastating disease.

The American Cancer Society encourages the Senate Financial Institutions and Insurance committee members to vote SB629 favorably.

FI&I Committee
February 26, 2008
Attachment 4

KANSAS HOSPITAL ASSOCIATION

Thomas L. Bell
President

February 26, 2008

TO: Senate Financial Institutions and Insurance Committee

FROM: Tom Bell
President

RE: Senate Bill 629

The Kansas Hospital Association appreciates the opportunity to provide comments regarding SB 629. This legislation clarifies that insurers are required to pay for routine patient care services in a clinical cancer research trial, if those same services would otherwise be covered.

A growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care received as a participant in a clinical trial. Lack of such coverage is a significant barrier to many patients who might otherwise enroll in a trial. Lack of coverage also makes it harder for researchers to successfully conduct trials that could improve prevention and treatment options.

It is important to note that these laws and agreements do not cover the research costs associated with the conduct of the trial, such as tests purely performed for research purposes. In most cases, such costs would be paid for by the group sponsoring the trial, such as the National Cancer Institute or a pharmaceutical company. Indeed, we are aware there is substantial evidence that legislation like SB 629 would not have an impact on health insurance premiums.

This policy is not without precedent. In 2000, Medicare began covering beneficiaries' patient care costs in clinical trials. In addition, the State Employee Health Plan provides such coverage.

We think that SB 629 helps to provide for increased access to care for a small, but important segment of the Kansas population without a corresponding increase in costs.

Thank you for your consideration of our comments.

FI&I Committee
February 26, 2008
Attachment 5

Kansas Hospital Association
215 SE 8th Ave. • P.O. Box 2308 • Topeka, KS • 66601 • 785/233-7436 • Fax: 785/233-6955 • www.kha-net.org

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Senate Financial Institutions & Insurance Committee: SB 629 – Coverage for Routine Care Associated with Cancer Clinical Trials

February 26, 2008

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Definition: Costs Related to Clinical Trials

- **Research/Clinical Trial costs:**
  - Costs associated with conducting clinical trial: data collection and management, research physician and nurse time, analysis of results, tests purely performed for research purposes. Such costs are usually covered by the sponsoring organization, such as the National Cancer Institute (NCI) or a pharmaceutical company.
- **Routine care costs**:
  - Costs for doctor visits, hospital stays, clinical laboratory tests, x-rays, etc., whether patient is participating in a trial or receiving standard treatment.

National Cancer Institute www.cancer.gov

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Background: Coverage of Routine Care

- **State Coverage:**
  - As of 2007, 20 States have passed legislation or instituted special agreements requiring health plans to cover cost of routine medical care for participants in clinical trials.
- **Federal Coverage:**
  - In 2000, Medicare began covering the cost of routine care for participants in cancer clinical trials. TriCare and the Veterans Administration also pay for the cost of routine care for participants in clinical trials.
- **Private Insurance Coverage.**
  - Lack of insurance coverage is a barrier for certain patients who might otherwise wish to be in a clinical trial for their cancer treatment. In one survey, 60% of patients said they feared having their insurance denied as a major reason for not signing up to take part in a clinical trial.

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Kansas State Employee Health Plan Coverage

- **Routine health care service costs covered.**
  - SEHP covers cost of routine health care services for patients enrolled in a clinical trial (not limited to cancer)
- **Clinical trials/research costs not covered.**
  - Coverage of cost of clinical trials are generally excluded from coverage.
- **Contract Language.**
  - Covered trials are referred to as "research urgent care."
  - Consists of treatment of life threatening or severely and chronically disabling conditions with a high probability of causing premature death when all other conventional treatments have failed.
  - Clinical trial treatment has to be clinically significant and show potential for substantial improvement in net health outcome compared to the most effective conventional treatment.

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State Employee Health Plan Costs

- **Cost of routine care not delineated.**
  - Because routine services pay under regular codes submitted to health plan, these expenses are lumped together with all other routine services.
- **Literature on cost of routine care:**
  - Most comprehensive research finds that treatment costs for clinical trial participants are on average 6.5% higher than what they would be if patients did not enroll. "Overall, the additional treatment costs of an open reimbursement policy for government-sponsored cancer clinical trials appear minimal[1]".

[1]Goldman et al (2003). **Incremental treatment costs in national cancer institute-sponsored clinical trials.** Journal of the American Medical Association.

Kansas Medicaid Coverage & Cost

- **Routine health care service costs covered.**
  - Medicaid covers cost of routine health care services for patients enrolled in a clinical trial (not limited to cancer)
- **Cost of Care not delineated**.
  - Because routine services pay under regular codes submitted, these expenses are lumped together with all other routine services.

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State of Kansas: Covers Routine Costs

- Clinical trials offer patients access to new and potentially life saving drugs and cures.
  - A ten percent drop in breast cancer mortality for women under the age of 50 is said to be the result of clinical trials research conducted in the 1970's.
  - The dramatic progress made in treating childhood cancers in recent years, is attributable, in part, to clinical trials, because 60 percent of all children with cancer are enrolled in some kind of trial.
  - For cancer patients, clinical trials are often the last resort after exhausting all other approved means of treatment.
- Participation in clinical trials is low -- only two to three percent of eligible adult patients enroll in clinical trials with health insurance coverage of routine care being a barrier.
- KHPA covers the cost of routine care for patients enrolled in a clinical trial in both the State Employee Health Plan and in Medicaid

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National Council of State Legislatures 2008
Coverage of Clinical Trials: Summary of State Laws

Table One provides a summary of the **20 states** that have enacted laws regarding mandated coverage of clinical trials.

Table One Clinical Trials Laws April 2006			
State Year of Enactment Bill Number and/or Citation	**Who is Required to Pay?**	**What Services or Benefits are Covered?**	**Other Key Criteria:**
Arizona (2000) Senate Bill 1213 20-2328	Hospital or medical service corporations, benefit insurers, health care service organizations, disability insurers, group disability insurers and accountable health plans	Patient costs associated with participation in Phase I through IV cancer clinical trials.	Trail must be reviewed by an Institutions Review Board in AZ. Health professional must agree to accept reimbursement from insurer as payment in full. Only covers trial when no clearly superior nonivestigational treatment exists. Trail must be in AZ.
California (2000) Senate Bill 37	All California insurers, including Medicaid and other medical assistance programs	Routine patient care costs associated with Phase I through IV cancer clinical trials.	May restrict coverage to services in CA.
Connecticut (2001) Senate Bill 325 Public Act 01-171	Private insurers, individual and group health plans	Routine patient care costs associated with cancer clinical trials.	Prevention trials are covered only in Phase III and only if involve therapeutic intervention. Insurer may require documentation of the likelihood of therapeutic benefit, informed consent, protocol information and/or summary of costs.
Delaware (2001)Senate Bill 181	Every group of blanket policy, including policies or contracts issued by health service corporations	Routine patient care costs for covered persons engaging in clinical trials for the treatment of life threatening diseases under specified conditions.	Trial must have therapeutic intent and enroll individuals diagnosed with the disease. Trial must not be designed exclusively to test toxicity or disease pathophysiology.
Georgia* (1998) 33-24-59.1	Insurers and the state health plan	Routine patient costs incurred in Phase II and III of prescription drug clinical trial programs for the treatment of children's	For the treatment of cancer that generally first manifests itself in children under the age of 19.

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		cancer.	
Illinois (1999) House Bill 1622 (amended 2004) Senate Bill 2339 Public Act No. 93-1000 20 ILCS 1405/56.3**	HMOs and individual/group insurance policies to offer coverage to the applicant or policyholder (2004 amendment: Plans may not be canceled or non renewed based on an individual's participation in a qualified clinical trial)	Routine patient care if the individual participates in an approved Phase II through IV cancer research trial.	Coverage benefit can have annual limit of $10,000. Trial must be conducted at multiple sites in state. Primary care MD must be involved in coordination of care. Researchers must submit results of trial for publication in nationally recognized scientific literature.
Louisiana (1999) RS 22:230.4	HMOs, PPOs, State Employee Benefits Program and other specified insurers	Patient costs incurred in Phase II through IV cancer clinical trials.	Only covers costs when no clearly superior, noninvestigational approach exists. Available data must support reasonable expectation that the treatment will be as effective as the noninvestigational alternative. Patient must sign an Institutional Review Board-approved consent form.
Maine (2000) 24-A-4310	Managed care organizations and private insurers	Routine patient care costs associated with clinical trial.	Participation must offer meaningful potential for significant clinical benefit. Referring physician must conclude that trial participation is appropriate.
Maryland*** (1998) Chap 146-15-827	Private insurers and other specified managed care organizations.	Patient costs for Phase I through IV cancer treatment, supportive care, early detection, and prevention trials. Phase II through IV for other life-threatening conditions, with Phase I considered on a case-by-case basis.	There is no clearly superior, nonivestigational alternative. The data provide a reasonable expectation that the treatment will be as least as effective as the alternative.
Massachusetts (2002) Chap 176A Sec 8X	All health plans issued or renewed after Jan. 1, 2003	Patient care services associated with all phases of qualified cancer clinical trials.	Insurers must provide payment for services that are consistent with the usual and customary standard of care provided under the trial's protocol and that would be covered if the patient did not participate in the trial.
Missouri (2002)	All health benefit plans operating in the state	Routine patient care costs as the result of Phase II, III or IV clinical trials for	There must be identical or superior nonivestigational treatment alternatives

376.429 (2006)- Phase II SB 567 & 792		the prevention, early detection, or treatment of cancer.	available before providing clinical trial treatment, and there must be a reasonable expectation that the trial will be superior to the alternatives. Requires coverage of FDA-approved drugs and devices even if they have not be approved for use in treatment of patient's particular condition.
New Hampshire (2000) 415:18	Private insurers and specified managed care plans	Medically necessary routine patient care costs incurred as a result of a treatment for Phase I through IV cancer clinical trial or trial for a life-threatening disease.	Coverage for Phases I or II decided on case-by-case basis. Coverage is required for services needed to administer drug or device under evaluation. Coverage is required for routine patient care associated with drugs or devices which are not subject of trial, as long as they have been approved by FDA.
Nevada (2003) (amended 2005)SB 29 NRS 695G.173	All health insurance insurers, medical service corporations, HMOs and managed care organizations	Patient costs associated with Phase I through IV cancer or chronic fatigue clinical trial	Healthcare facility and personnel must have experience and training to provide the treatment in a capable manner. There must be no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial. There must be a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment. Amendment revises type of medical treatment covered.
New Mexico (2002) (amended 2004 to delay repeal until July 1, 2009) 59A-22-43	A health insurer; a nonprofit health service provider; a HMO; a managed care organization; a provider service organization; or the state's medical assistance program.	Routine patient care costs incurred as a result of the patient's participation in a phase II, III or IV cancer clinical trial.	Must be undertaken for the purposes of the prevention of reoccurrence of cancer, early detection or treatment of cancer for which no equally or more effective standard cancer treatment exists. Must not be designed exclusively to test toxicity or disease pathophysiology and it has a therapeutic intent. Must be provided as part of a scientific study of a new therapy or intervention and is

			for the prevention of reoccurrence, early detection, treatment or palliation of cancer in humans and in which includes specific provisions of scientific study.
New Mexico (2001) 59A-22-43	Private insurers, specified managed care plans, and Medicaid and other state medical assistance programs	Routine patient care costs incurred as result of Phase I through IV cancer clinical trial.	Effective through July 1, 2004. Trial must have therapeutic intent. Reasonable expectation that investigational treatment will be at least as effective as standard treatment.
North Carolina (2001) ? 58-3-255	All health insurance plans and teachers' and state employees' comprehensive major medical plan.	Medically necessary costs of health care services associated with Phase II through IV of covered clinical trials.	Patients suffering from a life-threatening disease or chronic condition may designate a specialist who is capable of coordinating their health care needs.
Rhode Island (1994, 1997) 94-S 2623B 97-S 1A am	Private insurers and specified managed care plans	Coverage for new cancer therapies if treatment is provided under Phase II through IV cancer clinical trial.	
Tennessee (2005) HB 837	All health benefit plans	Routine patient care costs related to Phase I through IV cancer clinical trial.	Treament must involve drug that is exempt under federal regulations from a new drug application, or approved by: NIH, FDA in form of new drug application, DOD, or VA.
Vermont (2001) (amended 2005 to remove March 1, 2005 sunset provision) Chap 107 ? 4088b HB 6	All health insurance policies and health benefit plans, including Medicaid	Routine patient care costs incurred during the participation in a cancer clinical trial.	Providers and insurers required to participate in a cost analysis to determine impact of the program on health insurance premiums. Amended law allows for participation in trial outside of Vermont if patient notifies health benefit plan prior to participation, and no clinical trial is available at Vermont or New Hampshire cancer care providers.
Virginia (1999) ? 38.2-3418.8	Private insurers, specified managed care plans, and public employee health plans	Patient costs incurred during the participation in Phase II through IV cancer clinical trials. Coverage provided on a case-by-case basis for Phase I.	There must be no clearly superior, nonivestigational alternative. Data must provide a reasonable expectation that the treatment will be at least as effective as the alternative.
West Virginia (2003)	Individual and group insurers, health service	Patient costs associated with the participation in	Facility and personnel providing the treatment are

?9-2-12	corporations, health care corporations, HMOs, public employees insurance agency, Medicaid and the children's health insurance program	Phase II through IV clinical trial for treatment of life-threatening condition or the prevention, early detection and treatment of cancer.	capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise. There must be no clearly superior, noninvestigational treatment alternative. Data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative.
Wisconsin AB 617 (2006) Act 194	Any health insurance plan offered by the state, any self-insured plans	Routine patient care costs incurred during the participation in all phases of a cancer clinical trial. No policy, plan, or contract may exclude coverage for the cost of any routine patient care that is administered to an insured in a cancer clinical trial satisfying the criteria under par. (c) and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.	Trial must meet all criteria: 1. The purpose is to test whether the intervention potentially improves the trial participant's health outcomes. 2. The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes. 3. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology. 4. The trial does one of the following: a. Tests how to administer a health care service, item, or drug for the treatment of cancer. b. Tests responses to a health care service, item, or drug for the treatment of cancer. c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer. d. Studies new uses of health care services, items, or drugs for the treatment of cancer. 5. The trial is approved by one of the following: a. A National Institute of Health, or one of its cooperative groups or centers, under the federal department of health and human services; federal food and drug administration; federal department of defense; federal department of veterans affairs.

*In 2002, all major insurers in Georgia agreed to cover routine patient care costs associated with Phase I, II, III, or IV cancer clinical trials. Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. The agreement also provides for the

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coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established by any nationally recognized health care organization (see below).

**Illinois Executive Branch Administrative Code (20 ILCS 1405/1405-20) required the Department of Insurance to conduct an analysis and study of costs and benefits derived from the implementation of the coverage requirements for investigational cancer treatments. The study covered the years 2000 through 2002 and included an analysis of the effect of the coverage requirements on the cost of insurance and health care, the results of the treatments to patients, the mortality rate among cancer patients, any improvements in care of patients, and any improvements in the quality of life of patients.

***A 2003 Maryland law (S 128) repealed a reporting requirement for insurers, nonprofit health service plans, and HMOs to submit a report that described the trials covered during the previous year.

Sources: National Cancer Institute, Health Policy Tracking Service.

Summary of Other Actions

Table Two summarizes the special agreements some states have arranged with insurance companies to voluntarily provide coverage for clinical trials.

Table Two
Special Agreements

State (Year Agreement Became Effective) Web Address of Agreement	Who is Required to Pay?	What Services or Benefits are Covered?	Other Key Criteria:
Georgia (2002) Georgia Cancer Coalition	All major insurers	Routine patient care costs associated with Phase I through IV cancer clinical trials.	Trials include those that involve a drug that is currently exempt under federal regulations from a new drug application or those that are approved by specified federal agencies or a local institutional review board. Provides for the coverage of cancer screens and examinations in accordance with the most recently published guidelines and recommendations established by any nationally recognized health care organization.
Michigan (2002) Michigan Consensus Agreement	Private insurance plans, HMOs and Medicaid	Routine patient care costs associated with Phase II and III cancer clinical trials.	Coverage for Phase I trials is under consideration.
New Jersey (1999) New Jersey Consensus	All insurers	Routine patient care costs associated with all phases of cancer clinical trials.	

Agreement			
Ohio (1999) Ohio Med Plan	State employees on Ohio Med Plan	Routine patient care costs associated with Phase II and III cancer treatment clinical trials.	Preauthorization is required for clinical trial participation.

Kansas Insurance Department

Sandy Praeger, Commissioner of Insurance

TESTIMONY ON
SB 629

SENATE FINANCIAL INSTITUTIONS AND INSURANCE
February 26, 2008

Madam Chair and Members of the Committee:

The Kansas Insurance Department looks carefully at mandates because while they provide a needed benefit to some insureds, this benefit comes at the expense of other policyholders in the form of premium increases. In addition, mandates passed by the legislature can only impact the private insured population, which accounts for about 30% of Kansans, most of whom are in small groups (50 or fewer employees). However, Senate Bill 629 has provisions that will help in areas of cancer research and could potentially lower future costs at the same time.

SB 629 would require insurance companies to cover costs of procedures that are normally covered by the insurance company in the event that a patient is a participant in a clinical trial. Some insurance companies already cover this for most stages of the clinical trial. In cases like these the mandate may not have much of an impact on cost since the bill only requires insurance companies to cover those things that they would normally cover if a person was not in a clinical trial.

If an insurance company covers the cost of these standard procedures then this bill could actually encourage more patients to enter into cancer clinical trials, thus creating an opportunity for more research. These trails are a crucial part of cancer research in proving the effectiveness of new treatments and pharmaceuticals. As the Kansas University Medical Center competes for the prestigious national cancer center designation, this type of inclusion in insurance policies could help that effort. That being said, we still have some reservations about being outright advocates for this mandate. One concern is who would be covering the costs associated with potential adverse side effects of a clinical trial. We feel that this responsibility should not fall on the insurers, since covering these costs could increase premiums for every other policyholder. Perhaps the bill could clarify that any adverse side effects of the clinical trial will be taken care of as part of the clinical trial. It would be helpful to have some of these issues resolved as the bill moves forward.

SB 629 could be one step toward helping Kansas become a leader in cancer research, but unintended consequences could also increase insurance costs for all Kansans which is why we urge the committee to move forward with caution when considering the cancer clinical trials mandate.

Sandy Praeger
Commissioner of Insurance

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Kansas Association of Health Plans
Written testimony before the
Senate Financial Institutions and Insurance Committee
SB 629
February 26, 2008

Madam Chairperson and members of the Committee. Thank you for allowing me to submit testimony to you today on behalf of the Kansas Association of Health Plans (KAHP).

The KAHP is a nonprofit association dedicated to providing the public information on managed care health plans. Members of the KAHP are Kansas licensed health maintenance organizations, preferred provider organizations and other entities that are associated with managed care. KAHP members serve most all Kansans enrolled in private health insurance. KAHP members also serve the Kansans enrolled in HealthWave and Medicaid managed care. We appreciate the opportunity to provide comment on SB 629.

The KAHP is opposed to SB 629. This bill would require health plans to provide coverage for many services related to participation in a clinical trial. A few weeks ago several members of the KAHP met with the proponents of this bill. At that time the proponents explained that they were only seeking coverage for "routine costs" for services that would otherwise be covered had the patient continued routine cancer treatment and not chosen to participate in a clinical trial. Many plans currently provide this coverage for phase 2, 3 & 4 clinical trials. The few that don't were quite close to joining the majority of the plans and are still considering the change. The request seemed quite reasonable and steps were being taken to initiate the change. One avenue that was and is still being pursued is for the Insurance Commissioner to issue a formal direction to plans requiring them to cover the routine costs of care normally provided a cancer patient according to certain protocols.

The Legislation before you goes far beyond requiring "routine costs" be covered. The following are examples:

New Section 1 (a) (4) (A): This section defines "patient care services". The definition requires plans to pay for drugs, devices, services, etc that would otherwise be covered under the individual's contract if the individual was not enrolled in a clinical trial. According to this definition a plan would be required to pay for services currently paid for by the sponsor of the trial, simply because the services would otherwise be covered under the health insurance contract for any other reason. (Example additional MRI's).

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New Section 1 (a) (4) (A) (ii) requires to plans to pay for monitoring of the experimental treatment, etc.

New Section 1 (a) (4) (A) (iii) requires plans to pay for prevention complications arising from the clinical trial. These complications would not be present absent the clinical trial, therefore how can they be "routine costs"?

New Section 1 (b) expands the required coverage to pilots and feasibility trials.

New Section 1 (j) allows patients to participate in trials with providers outside of the plans negotiated network.

This bill is another example hard decisions health plans must make when offering health insurance to Kansas individuals, families and employers. As with all most other Legislative Sessions in my 10 years representing the KAHP, many bills have been introduced or discussed this Session requesting you to mandate plans cover more. Examples include increased mental health coverage, mandating coverage for hearing aids, nutritional formulas, colon cancer screening, autism, bariatric surgery, wigs and telemedicine services. In addition, a bill in the House would mandate plans reimburse additional providers including professional counselors and marriage and family therapists. All of these bills, including SB 629, are proposals demanding that private health plans and your constituents who pay the insurance premiums pay for more services or providers. The system can only pay for so much otherwise health insurance becomes even more unaffordable for those currently struggling to maintain insurance for themselves or in the case of a business owner, their employees and their families.

In addition, this bill does not meet the requirements set forth in statute requiring a cost impact report be performed prior to the legislature considering a mandate bill (KSA 40-2248) and other legislation requiring the testing of any new mandate first on the state employees health plan in order to help determine its cost impact commonly called the "test track" legislation (KSA 40-2249a). If you determine that this particular mandate is wise and more important than the others, we ask that you require the proponents to follow current law and submit a cost impact study and agree to test track the requirement first on the state employees' health plan to help protect your constituents and our policyholders from unwise and uneconomical state mandates.

The KAHP urges you to oppose this and other compelling requests for increased coverage and instead continue to partner with the KHPA, health plans and other interested parties attempting to seek ways to halt the growing number of uninsured. Requiring health insurance to pay more providers or pay for additional services and treatments is a step in the opposite direction. Thank you and I'll be happy to answer any questions you may have.

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Shalton | Flanigan | Suelthaus PC

Memorandum

TO: THE HONORABLE RUTH TEICHMAN, CHAIR
SENATE FINANCIAL INSTITUTIONS AND INSURANCE COMMITTEE

FROM: WILLIAM W. SNEED, LEGISLATIVE COUNSEL
AMERICA'S HEALTH INSURANCE PLANS

RE: S.B. 629

DATE: FEBRUARY 26, 2008

Madam Chair, Members of the Committee: My name is Bill Sneed and I am Legislative Counsel for America's Health Insurance Plans ("AHIP"). AHIP is a trade association representing nearly 1,300 member companies providing health insurance coverage to more than two million Americans. Our member companies offer medical expense insurance, long-term care insurance, disability income insurance, dental insurance, supplemental insurance, stop-loss insurance and reinsurance to consumers, employers and public purchasers. Please accept this memorandum as our opposition to S.B. 629.

Notwithstanding the good intentions behind the introduction of S.B. 629, we believe its enactment is unnecessary, and in certain instances may hamper the utilization of clinical trials. We would content that this mandate is unnecessary for the following reasons.

First, health plans already provide appropriate access to clinical trials, making mandating legislation unnecessary. Almost all insurers examine the appropriateness of coverage for clinical trials on a case-by-case basis. When insurers determine that coverage is in the patient's best interest, they typically cover the cost of routine care associated with the trial and care that would have been otherwise provided.

Second, because clinical trials evaluate the safety and efficacy of new therapies, it is critical that trials be designed in ways that maximize patient safety. A legislative mandate to cover clinical trials runs the risk of requiring coverage of trials that are unsafe for patients. Health plans have the infrastructure and expertise, developed by working with independent experts, to identify and weed out trials that do not meet the criteria established by the National Institutes of Health, and thus threaten to jeopardize patient safety. Without this discretion, health plans could be forced to cover trials that may in fact harm patients.

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Next, a legislative mandate to cover clinical trials is likely to increase the cost of health coverage, given that there are numerous procedures, tests and laboratory work that are performed more frequently in the context of the trial than under standard therapy. Thus, it becomes difficult for the health plan to determine what patient care service would otherwise be covered under the health plan but for the enrollment within a clinical trial.

Finally, a legislative mandate imposes a "one size fits all" approach to covering clinical trials when, in fact, all trials are not created equally. If, however, the Committee believes it should move forward and work S.B. 629, we would make the following specific recommendations that should be included in this bill.

First, we would urge that Kansas mirror the mandate that is currently implemented in the State of Missouri inasmuch as my clients are multistate carriers, and by doing so, there would be some lessening of the administrative burden of implementing this mandate. This would limit the reimbursement for reasonable costs otherwise covered for Phase II, III or IV clinical trials.

Although we believe it totally inappropriate to have this mandate cover Phase I clinical trials, if the Committee entertains that option we would urge the Committee to include the criteria for the payment of Phase I trials that has been implemented by CMS, which is very stringent as to what the trial is designed to test for, thus having a therapeutic intent. Otherwise, it is our contention that insurers would be paying for expenses associated with a trial that is truly "experimental."

We appreciate the opportunity to present this testimony and we urge the Committee to take no action on S.B. 629.

I am available for questions at your convenience.

Respectfully submitted,

William W. Sneed

WWS:kjb