Date

### MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman James Barnett at 1:30 P.M. on February 15, 2007 in Room 231-N of the Capitol.

All members were present.

## Committee staff present:

Emalene Correll, Kansas Legislative Research Department Terri Weber, Kansas Legislative Research Department Nobuko Folmsbee, Office of Revisor of Statutes Morgan Dreyer, Committee Secretary

# Conferees appearing before the committee:

Jerry Slaughter, Kansas Medical Society David Wilson, AARP Nancy Zogleman, representing Andrea Douglas, PhRMA

#### Others attending:

See attached list.

Upon calling the meeting to order, Chairman Barnett asked that the Committee review the Minutes for February 14, 2007 for approval at the end of the meeting.

The Chair then announced that the next order of business would be to open the hearing on SB 285.

# Hearing on <u>SB 285 – An act concerning the healing arts act; prohibiting billing from anatomic pathology services in certain circumstances</u>

The fiscal note for <u>SB 285</u> was available for the Committee to view. A copy of the fiscal note is (<u>Attachment 1</u>) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett called upon proponent conferee, Jerry Slaughter, Kansas Medical Society who stated that the bill would add a new section to the Healing Arts Act making it unprofessional conduct for a physician to bill a patient for certain pathology (laboratory) services unless those services were personally rendered by the physician, or unless the services were provided under the physician's direct supervision. A copy of his testimony is (Attachment 2) attached hereto and incorporated into the Minutes as references.

The Chair closed the hearing on SB 285.

The motion was made by Senator Schmidt to move the bill out favorably. It was seconded by Senator Brungardt and the motion carried.

# Action on <u>SB 201 – An act concerning restriction on person maintaining or residing, working or volunteering at child care facilities or family day care homes</u>

Chairman Barnett called upon Nobuko Folmsbee to explain the balloon for <u>SB 201</u>. Nobuko handed the Committee the draft of the bill with the new changes. A copy of the draft is (<u>Attachment 3</u>) attached hereto and incorporated into the Minutes as referenced.

Materials from the  $\underline{SB\ 201}$  hearing were included for the members to review. A copy of the materials are (Attachment 4) attached hereto and incorporated into the Minutes as referenced.

The motion was made by Senator Schmidt to accept the amendment and move the bill out favorably. It was seconded by Senator Brungardt and the motion carried.

# Action on SB 202 - An act concerning child care facilities; relating to definitions

Chairman Barnett called upon Nobuko Folmsbee to read the changes for SB 202. A draft of the bill with the

#### **CONTINUATION SHEET**

MINUTES OF THE Senate Public Health and Welfare Committee at 1:30 P.M. on February 15, 2007 in Room 231-N of the Capitol.

new changes were given out to the Committee. A copy of the draft is (<u>Attachment 5</u>) attached hereto and incorporated into the Minutes as referenced.

Materials from the <u>SB 202</u> hearing were included for the members to review. A copy of the materials are (<u>Attachment 6</u>) attached hereto and incorporated into the Minutes as referenced.

The motion was made by Senator Schmidt to accept the amendment and move the bill out favorably. It was seconded by Senator Jordan and the motion carried.

# Action on SB 284 - An act concerning the radiologic technologists practice act

The Chair called upon Nobuko Folmsbee to explain <u>SB 284</u>. A draft of the bill with the new changes were given out to the Committee. A copy of the draft is (<u>Attachment 7</u>) attached hereto and incorporated into the Minutes as referenced.

Materials from the <u>SB 284</u> hearing were included for the members to review. A copy of the materials are (<u>Attachment 8</u>) attached hereto and incorporated into the Minutes as referenced.

The Chair called the Committee's attention to a letter submitted by Lawrence Buening, Kansas Board of Healing Arts. The Chair ask that Larry come before the Committee to explain his testimony. A copy of his testimony is (Attachment 9) attached hereto and incorporated into the Minutes as referenced.

The motion was made by Senator Brungardt to accept the amendment and move the bill out favorably. It was seconded by Senator Wagle and the motion carried.

Chairman Barnett then opened the hearing on SB 229.

# Hearing on <u>SB 229 – An act concerning prescription drugs; creating the prescription confidentiality act</u>

The fiscal note for <u>SB 229</u> was available for the Committee to view. A copy of the fiscal note is (<u>Attachment</u> 10) attached hereto and incorporated into the Minutes as referenced.

The Chair called upon Nobuko Folmsbee to read and explain **SB 229** for the Committee.

Questions for Nobuko came from Senators Schmidt, Barnett, and Emalene Correll regarding HIPPA, remedies for Consumer Protection Act, and collection of data.

Chairman Barnett called upon proponent conferee, David Wilson, AARP - Kansas who stated that this bill will help maintain the privacy between a doctor and patient and enable doctors not to be targeted by drug manufacturers to increase sales without regard to efficacy. A copy of his testimony is (Attachment 11) attached hereto and incorporated into the Minutes as referenced.

Questions came from Senators Schmidt, and Barnett regarding other States that have passed similar legislation, physicians requests, opposition position by AMA, medicaid prescribing habits.

The Chair called upon opponent conferee, Nancy Zogleman representing on behalf of Andrea Douglas, PhRMA who stated that this bill restricts pharmaceutical manufacturer use of prescriber data. A copy of her testimony is (Attachment 12) attached hereto and incorporated into the Minutes as referenced.

Questions came from Senators Brungardt and Barnett regarding how information is acquired on an individual prescriber, off-label use, preverse process, counter detailing, prescriber education program.

Chairman Barnett then closed the hearing on SB 229.

The Chair announced that the final item on the agenda was for the Minutes to be approved for the Senate

# CONTINUATION SHEET

MINUTES OF THE Senate Public Health and Welfare Committee at 1:30 P.M. on February 15, 2007 in Room 231-N of the Capitol.

Public Health and Welfare Committee on February 14, 2007.

The motion was made by Senator Haley to approve the Minutes. It was seconded by Senator Gilstrap and the motion carried.

# Adjournment

As there was no further business, the meeting was adjourned at 2:25 p.m.

The next meeting is scheduled for February 21, 2007.

# Senate Public Health and Welfare Committee Please Sign In Feb. 15, 2007

Please Sign In

Mark Synorec, MD	
Julie Hein	Hoin Law Firm
LARRY BUENING	BD DF HEALING ARTS
Glad Smoot	Ifizer
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The Horber	Plune_
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Nancy Zogleman	Prizer
Parol A. Curtis	AstraZene ce
Austin- Hayden	Su. Brugalt
R.S. McKenna	52.3
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Susan Kon	
Will Deer	Federico Consoláins
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February 14, 2007

The Honorable Jim Barnett, Chairperson Senate Committee on Public Health and Welfare Statehouse, Room 120-S Topeka, Kansas 66612

Dear Senator Barnett:

SUBJECT: Fiscal Note for SB 285 by Senate Committee on Public Health and Welfare

In accordance with KSA 75-3715a, the following fiscal note concerning SB 285 is respectfully submitted to your committee.

SB 285 would amend the Healing Arts Act to prohibit any person from charging a patient, patient's representative, or insurer a fee to cover the cost of anatomic pathology services if the services are not performed by a person licensed to practice medicine and surgery or a person who is an approved staff member of a licensed clinical laboratory. Anatomic pathology services would include the examination of human organ tissue samples or cells that make up human fluids. The bill would also define unprofessional conduct, false advertisement, and professional incompetence as it would relate to anatomic pathology services.

The Board of Healing Arts indicates that the passage of SB 285 would not have a fiscal effect on agency operations.

Sincerely,

Duane A. Goossen
Director of the Budget

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cc: Cathy Brown, Healing Arts



623 SW 10th Avenue Topeka, KS 66612-1627 785.235.2383 800.332.0156 fax 785.235.5114

www.KMSonline.org

To:

Senate Public Health and Welfare Committee

From:

Jerry Slaughter

Executive Director

Subject:

SB 285; concerning billing for anatomic pathology services

Date:

February 15, 2007

The Kansas Medical Society appreciates the opportunity to appear today on SB 285, which would add a new section to the Healing Arts Act making it unprofessional conduct for a physician to bill a patient for certain pathology (laboratory) services unless those services were personally rendered by the physician, or unless the services were provided under the physician's direct supervision.

This issue arose because of some billing practices in other states which involved the inappropriate marking up of certain laboratory services by physicians. In those states, a few physician practices had charged the patient substantially more than the amount billed to the practice by the pathologist or laboratory that performed the tests. Charging for such services in this manner is unethical, and it also is impermissible in both the Medicare and Medicaid programs.

Frankly, we do not have any evidence that this practice exists in Kansas, but we felt that it would make sense to be proactive and make it clear that such practices are inappropriate. Similar legislation has been passed in over a dozen states, and several more are actively considering such legislation. This legislation is the work of an ad hoc committee of physicians from five medical specialty organizations we convened last year to discuss this issue. After studying the issue, the committee recommended to our Board that this legislation be enacted. If enacted, the bill would make it unprofessional conduct, and a ground for licensure sanctions, to bill for anatomic pathology services that aren't either performed personally by the physician, or performed under his or her direct supervision. It is our belief that existing provisions in the Healing Arts Act could be interpreted to cover this situation, but to make it abundantly clear, we felt a new subsection specific to this issue should be adopted.

We would respectfully urge the Committee to report SB 285 favorably for passage. Thank you for the opportunity to present these comments.

Senate Rublic Health and Welfare Committee Attachment # Z February 15, 2007 lession of 2007

# **SENATE BILL No. 201**

## By Committee on Public Health and Welfare

#### 1-25

AN ACT concerning restrictions on persons maintaining or residing, working or volunteering at child care facilities or family day care homes; amending K.S.A. 2006 Supp. 65-516 and repealing the existing section; also repealing K.S.A. 2006 Supp. 65-516a.

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

Section 1. K.S.A. 2006 Supp. 65-516 is hereby amended to read as follows: 65-516. (a) No person shall knowingly maintain a child care facility or maintain a family day care home if, in the child care facility or family day care home, there resides, works or regularly volunteers any person who in this state or in other states or the federal government:

- (1) (A) Has a felony conviction for a crime against persons, (B) has a felony conviction under the uniform controlled substances act, (C) has a conviction of any act which is described in articles 34, 35 or 36 of chapter 21 of the Kansas Statutes Annotated, and amendments thereto or a conviction of an attempt under K.S.A. 21-3301 and amendments thereto to commit any such act or a conviction of conspiracy under K.S.A. 21-3302, and amendments thereto, to commit such act, or similar statutes of other states or the federal government, or (D) has been convicted of any act which is described in K.S.A. 21-4301 or 21-4301a and amendments thereto or similar statutes of other states or the federal government;
- (2) has been adjudicated a juvenile offender because of having committed an act which if done by an adult would constitute the commission of a felony and which is a crime against persons, is any act described in articles 34, 35 or 36 of chapter 21 of the Kansas Statutes Annotated, and amendments thereto, or similar statutes of other states or the federal government, or is any act described in K.S.A. 21-4301 or 21-4301a and amendments thereto or similar statutes of other states or the federal government;
- (3) has committed an act of physical, mental or emotional abuse or neglect or sexual abuse as validated and who is listed in the child abuse and neglect registry maintained by the department of social and rehabilitation services pursuant to K.S.A. 38-1523 2006 Supp. 38-2226 and amendments thereto and (A) the person has failed to successfully complete a corrective action plan which had been deemed appropriate and

Nobuko Folmsbee

Senate Public Health and Welling Attachment #3

- approved by the department of social and rehabilitation services, or (B) the record has not been expunged pursuant to rules and regulations adopted by the secretary of social and rehabilitation services;
- (4) has had a child declared in a court order in this or any other state to be deprived or a child in need of care based on an allegation of physical, mental or emotional abuse or neglect or sexual abuse;
- (5) has had parental rights terminated pursuant to the Kansas juvenile code or K.S.A. 38-1581 through 38-1584 2006 Supp. 38-2266 through 38-2270, and amendments thereto, or a similar statute of other states;
- (6) has signed a diversion agreement pursuant to K.S.A. 22-2906 et seq., and amendments thereto, or an immediate intervention agreement pursuant to K.S.A. 2006 Supp. 38-2346, and amendments thereto involving a charge of child abuse or a sexual offense; or
  - (7) has an infectious or contagious disease.

- (b) No person shall maintain a child care facility or a family day care home if such person has been found to be a person in need of a guardian or a conservator, or both, as provided in K.S.A. 59-3050 through 59-3095, and amendments thereto.
- (c) Any person who resides in a child care facility or family day care home and who has been found to be in need of a guardian or a conservator, or both, shall be counted in the total number of children allowed in care.
- (d) In accordance with the provisions of this subsection (d), the secretary of health and environment shall have access to any court orders or adjudications of any court of record, any records of such orders or adjudications, criminal history record information including, but not limited to, diversion agreements, in the possession of the Kansas bureau of investigation and any report of investigations as authorized by subsection (e) of K.S.A. 38-1523 2006 Supp. 38-2226 and amendments thereto in the possession of the department of social and rehabilitation services or court of this state concerning persons working, regularly volunteering or residing in a child care facility or a family day care home. The secretary shall have access to these records for the purpose of determining whether or not the home meets the requirements of K.S.A. 59-2132, 65-503, 65-508, 65-516 and 65-519 and amendments thereto.
- (e) In accordance with the provisions of this subsection (e), the secretary is authorized to conduct national criminal history record checks to determine criminal history on persons residing, working or regularly volunteering in a child care facility or family day care home. In order to conduct a national criminal history check the secretary shall require fingerprinting for identification and determination of criminal history. The secretary shall submit the fingerprints to the Kansas bureau of investigation and to the federal bureau of investigation and receive a reply to

- enable the secretary to verify the identity of such person and whether such person has been convicted of any crime that would prohibit such person from residing, working or regularly volunteering in a child care facility or family day care home. The secretary is authorized to use information obtained from the national criminal history record check to determine such person's fitness to reside, work or regularly volunteer in a child care facility or family day care home.
- (f) No child care facility or family day care home or the employees thereof, shall be liable for civil damages to any person refused employment or discharged from employment by reason of such facility's or home's compliance with the provisions of this section if such home acts in good faith to comply with this section.

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- (f) (g) For the purpose of subsection (a)(3), an act of abuse or neglect shall not be considered to have been validated by the department of social and rehabilitation services unless the alleged perpetrator a person listed in the child abuse and neglect central registry shall not be prohibited from residing, working or volunteering in a child care facility or family day care home unless such person has: (1) Had an opportunity to be interviewed and present information during the investigation of the alleged act of abuse or neglect; and (2) been given notice of the agency decision and an opportunity to appeal such decision to the secretary and to the courts pursuant to the act for judicial review and civil enforcement of agency actions.
  - (h) In regard to Kansas issued criminal history records:
- (1) The secretary of health and environment shall provide in writing information available to the secretary to each child placement agency requesting information under this section, including the information provided by the Kansas bureau of investigation pursuant to this section, for the purpose of assessing the fitness of persons living, working or regularly volunteering in a family foster home under the child placement agency's sponsorship.
- (2) The child placement agency is considered to be a governmental entity and the designee of the secretary of health and environment for the purposes of obtaining, using and disseminating information obtained under this section.
- (3) The information shall be provided to the child placement agency regardless of whether the information discloses that the subject of the request has been convicted of any offense.
- (4) Whenever the information available to the secretary reveals that the subject of the request has no criminal history on record, the secretary shall provide notice thereof in writing to each child placement agency requesting information under this section.
  - (5) Any staff person of a child placement agency who receives infor-

(f) The secretary shall notify the child care facility, within seven days by restricted mail with return receipt requested, when the result of the national criminal history record check or other appropriate review reveals unfitness specified in subsection (a) (1) through (7) with regard to the person who is the subject of the review.

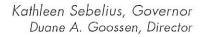
And reletter the remaining subsections accordingly

mation under this subsection (h) shall keep such information confidential, except that the staff person may disclose such information on a need-to-know basis to: (A) The person who is the subject of the request for information, (B) the applicant or operator of the family foster home in which the person lives, works or regularly volunteers, (C) the department of health and environment, (D) the department of social and rehabilitation services, (E) the juvenile justice authority, and (F) the courts.

- (6) A violation of the provisions of subsection (h)(5) shall be an unclassified misdemeanor punishable by a fine of \$100 for each violation.
- Sec. 2. K.S.A. 2006 Supp. 65-516 and 65-516a are hereby repealed.
- Sec. 3. This act shall take effect and be in force from and after its publication in the statute book.

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http://budget.ks.gov

February 9, 2007

The Honorable Jim Barnett, Chairperson Senate Committee on Public Health and Welfare Statehouse, Room 120-S Topeka, Kansas 66612

Dear Senator Barnett:

SUBJECT: Fiscal Note for SB 201 by Senate Committee on Public Health and Welfare

In accordance with KSA 75-3715a, the following fiscal note concerning SB 201 is respectfully submitted to your committee.

SB 201 would permit the Department of Health and Environment (KDHE) to conduct national criminal history record checks and would allow KDHE to require fingerprints to determine criminal history and a person's eligibility to live, work, or volunteer in child care facilities and family day care homes. The bill would also allow KDHE to share the results of background checks with child placement agencies for the purpose of adoption and to assess the suitability of prospective foster parents to become licensed.

KDHE states that there would be no direct fiscal effect for the agency. However, the bill is necessary to comply with the federal requirements for national background checks contained in the Adam Walsh Act. If these federal requirements are not met, the agency could be in danger of losing federal Title IV-E Foster Care funds.

Child placement agencies, which are not operated by the state, estimate savings of \$9,000 because they would no longer have to duplicate background checks from the KBI. However, fingerprints based national background check costs could be as much as \$50 per individual. This cost would be borne by the foster or adoptive family, or the child placement agency.

Sincerely,

Duane A. Goossen
Director of the Budget

cc: Aaron Dunkel, Health & Environment Linda Durand, KBI

900 S.W. Jackson Street, Room 504-N, Topeka, KS 66612 • (785) 296-2436 • Fax: (785) e-mail: duane.goossen@hudget.ks.gov

senate Ruble Heath and Commits Attachment #4 rebruurs 15, 2007



DEPARTMENT OF HEALTH AND ENVIRONMENT Kathleen Sebelius, Governor Roderick L. Bremby, Secretary

www.kdheks.gov

Division of Health

#### Testimony on SB 201

To

Senate Committee on Public Health and Welfare

By Christine Ross-Baze LMSW, Director Child Care Licensing and Registration Program

Kansas Department of Health and Environment

## February 14, 2007

Chairman Barnett and members of the Committee on Public Health and Welfare, my name is Christine Ross-Baze and I am the director of the Child Care Licensing and Registration Program at the Kansas Department of Health and Environment. Thank you for the opportunity to appear before you today in support of Senate Bill 201.

SB 201 amends K.S.A. 65-516 in a number of ways.

The bill proposes amended language to update the terms used in K.S.A. 65-516 and to update needed statutory references.

Language has been added to clarify the Department's authority to prohibit a person from residing, working or volunteering in a child care facility or family day care home if the person has a criminal conviction, juvenile adjudication or child abuse or neglect determination in another state or the federal government that Kansas would consider to be a prohibiting offense if it occurred in Kansas.

On page 1 lines 25 and 26 the bill proposes to add a conviction of conspiracy to commit a prohibiting offense to the list of prohibiting conditions. This addition will better protect children cared for in child care facilities and family day care homes.

SB 201 proposes to permit the Department to conduct national criminal history record checks to determine criminal history and a person's eligibility to reside, work or regularly volunteer in BURFALL DIGARE AND FIFALT HAVE ACILITIES OF HIGH CARE FICTINSING REGISTRATION PROGRAM CURTIS STATE OFFICE BUILDING, 1000 SW JACKSON ST., STE. 200, TOPEKA, KS 66612-1270 require fingerprints for identification purposes and to conduct the national criminal history background checks.

New federal legislation, the Adam Walsh Act of 2006, requires that states conduct national criminal history background checks for all prospective foster and adoptive parents and adults living in the foster or adoptive home. The proposed language in SB 201 is designed to comply with the federal requirements.

On page 3 beginning with line 24, SB 201 proposes to require the Department to share the results of the background checks with child placement agencies for the purposes of adoption and to assess the suitability of prospective foster parents to become licensed. With this provision child placement agencies would not need to request background checks separately from the Department's process. This efficiency would benefit children and families by reducing duplication and resultant delays. The recommendation for this efficiency originated from discussions in the Foster Parent Best Team involving child placement agencies, foster parents, SRS and the Department. Child placement agency staff estimated that this efficiency would save the agencies approximately \$9,000 in conducting duplicative background checks.

The Department supports the passage of SB 201. I am available to answer any questions you may have.

# Kansas Department of

# Social and Rehabilitation Services

Don Jordan, Secretary

Senate Public Health and Welfare Committee February 14, 2007

Senate Bill 201

Integrated Service Delivery-Children and Family Services

Deputy Secretary Candy Shively

For additional information contact:
Public and Governmental Services Division
Kyle Kessler, Deputy Secretary

Docking State Office Building 915 SW Harrison, 6<sup>th</sup> Floor North Topeka, Kansas 66612-1570 phone: 785.296.0141

fax: 785.296.4685 www.srskansas.org

# Kansas Department of Social and Rehabilitation Services Don Jordan, Secretary

Senate Public Health and Welfare Committee February 14, 2007

#### Senate Bill 201

Senator Barnett and members of the committee, I'm Candy Shively, Deputy Secretary of SRS. Thank you for the opportunity to speak in support of SB 201.

Federal law now requires states, prior to licensing foster homes, to conduct finger print back ground checks with the National Crime Information Center (NCIC) of the Federal Bureau of Investigation (FBI), the Kansas child abuse and neglect registry and the child abuse and neglect registry of any other state in which a potential foster parent resided during the preceding 5 years. Failure to comply by July 1, 2007 may result in a loss of federal funds. These funds are safeguarded by the changes in new section (e). Additional changes contained in SB 201 are unrelated to federal funding.

The amendments to section (a)(3) and (g) don't substantively change the law, but do add clarity. Currently there is no reference to the child abuse and neglect registry in Kansas statutes. The name grew out of the addition of subsection (3) in 1984. Social and Rehabilitation Services (SRS) didn't use the term validated in 1984 and doesn't currently use that term. This has been confusing for some who are barred by K.S.A. 65-516(a)(3) because their names are in the registry based on a substantiated finding of abuse or neglect. This change, carried over in section (g), more accurately communicates the cause and effect of an SRS determination of abuse or neglect.

We appreciate the efforts of the Kansas Department of Health and Environment to safeguard this federal funding stream for Kansas and ask your support of SB 201.

I would be happy to answer any questions.



Kansas Advocates for Better Care

Board of Directors

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Vice-President: Molly Wood, JD, Lawrence Elder Law Attorney

Treasurer: Evie Curtis, Overland Park Senior Vice-President/Trust Officer

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> Eloise Lynch, Salina Retired teacher & Kansas Legislator

Marilyn & Ollie Brashears Kansas City Alverta McField Nursing Home Support Group

> Earl Nehring, Ph.D., Lawrence Retired Professor of Political Science

Jeanne Reeder, LMSW MRE Overland Park Heart of America Alzheimer's Assn.

Artie Shaw, Ph.D., Lawrence Clinical Psychologist

Jean Wambsganss, Hutchinson Retired Nursing Home Activities/ Social Service Director

> Julia Wood, Wichita Retired Kansas teacher

Honorary Board Member William Dann, Lawrence

Executive Director Deanne Bacco, MCP, LACHA SB 201

Restricting persons maintaining, residing, working or volunteering at child care facilities or family day care homes

Testimony to the Senate Public Health and Welfare Committee From Kansas Advocates for Better Care February 14, 2007

Honorable Chairman Dr. Barnett and Committee Members:

Kansas Advocates for Better Care (KABC) is a proponent of this bill.

This bill is a welcome addition to the concept of protecting the members of these vulnerable populations from abuse, neglect and exploitation.

KABC humbly requests that you add one additional vulnerable population to this bill, frail adults/elders. Please include "licensed adult care home facilities" along with the child care facilities and family day care homes throughout the bill's descriptions of protected populations. We request that the bill be considered "an act concerning restrictions on persons maintaining or residing, working or volunteering at child care facilities, family day care homes, and licensed adult care homes".

Thank you for this opportunity to testify in support of this bill and request the same protection be provided for frail adults/elders living in licensed adult care homes.

Deanne Bacco, Executive Director of KABC

# SB-201 Proponent

Craig Barbee 1021 Lincoln St. Emporia Kansas 66801

S 0201

Bill by Public Health and Welfare

Child placement agencies; secretary of health and environment; information on persons at child care facilities or family day care homes.

I stand in favor of SB-201. I am Chairman of the Board of Emporia Christian School. We have a licensed day care facility a well as a K-4 through 8<sup>th</sup> grade elementary school.

While reviewing our processes with our administrator, I asked what type of responses we receive from the KDHE when we submitted requests for background checks. His reply was that we don't receive any responses from KDHE. I followed up asking how do we know that they received our requests and how do we know that the request was completed? KDHE informs the requesting facilities only if a negative response is obtained from the KBI.

I began to investigate the process that allowed such a large gap in communications and that is when I learned about the type of background checks that were being performed.

Currently, the KDHE only performs Criminal History checks on Kansas convictions. What that means are persons that have committed crimes that would prohibit them from having contact with children, in another state, could move to Kansas and resume contact with children and never show up on Kansas criminal history checks until they have committed a crime in Kansas and been caught and convicted.

When I discovered this, I had several contacts with the KDHE via email and telephone. In each conversation the KDHE representative replied that even though he may have agreed to some extent with my concerns, they were complying with all of their statutory and regulatory requirements (paraphrased).

My challenge to them was that they are tasked with protecting the most vulnerable of our citizens, our elderly and our children. If they new that there were gaps in their current system, they should correct them without being forced by a Regulatory change.

Is SB 201 enough or is there more that needs to be done to protect our most vulnerable citizens? The answer is no!

During my initial inquiry about the Criminal History checks I learned that once our facility places our request in the mail, that is the last we would see any communication on it unless it successfully arrived at KDHE; they successfully forwarded it on to the KBI and the KBI found a problem and replied to the KDHE and they replied to us. The

KDHE's view is that 'no news is good news'. This philosophy is placing Kansas children at risk. When I asked what would happen if we unknowingly hired someone with a criminal history, based upon the failed process of the KDHE, I was told that we would be liable. How can any child care or adult care facility function to hire additional staff or volunteers if they know that the KDHE is not keeping up their part of the bargain and they will hold that facility responsible for the KDHE's failure?

There is no proof that the KDHE ever received our request, then no time frame for them to complete the requested background check. There is currently no requirement for them to acknowledge that a child care facility ever sent them the request.

Although our US Postal Service is nearly flawless, we know that there are problems since they staff a full time Dead Letter Office. We also know that interoffice mail can be dropped in delivery, it can be misfiled, and it can be accidentally discarded.

I am proposing that we amend SB-201 to include the following:

- 1) Require KDHE to send a receipt notice to each requesting facility, acknowledging that they are starting the process of completing the criminal history checks on the persons listed. That notice of receipt should be made within 3 business days.
- Require a notice of completion of the requested criminal history checks when returned from the KBI. That reply should be made regardless of the results either positive or negative.
- 3) Require that if a negative result is obtained from the criminal history check, a direct communication is made to the requesting facility via a person to person communication. This would be followed with a specific written document identifying the results.

In conclusion, I support SB-201 as an improvement to our current system of protecting those most vulnerable of Kansas citizens, yet I must conclude additional measures must be taken to close the communication gap. If you pass SB-201 without ensuring the communication gap is closed, your time will be wasted and more importantly our children and elderly will still be at risk.

Robert Drummond TLC for Children and Families, Inc. President



Bruce Linhos Executive Director

Community Agencies Serving Children and Families

212 S.W. 7th Street

Topeka, Kansas 66603

(785) 235-KIDS

fax: (785) 235-8697

e-mail: blinhos@childally.org

Website: www.childally.org

Testimony in Support of SB 201 Senate Public Health and Welfare February 14, 2007

The Children's Alliance is the state's association of private non profit child welfare agencies. Member agencies provide an array of service for youth both in the custody of the Department of Social and Rehabilitation Services as well as those under the Juvenile Justice Authority. Services provided by member agencies include family preservation, foster care, group and residential treatment as well as specialized treatment services including drug and alcohol treatment. As an Association whose members serve youths in need of foster care, we support the intent of SB 201 to streamline the process of doing criminal justice checks on prospective foster parents. We also note that a similar bill HB 2497 passed out of the House Public Health Committee last year.

Agencies must do a criminal background check through the KBI of all prospective foster and adoptive parents. Currently we have approximately 2,200 foster homes. This bill will help expedite the process by which the child placing agencies receive this information on the KBI checks. When someone is volunteering to be a foster family what we want is to help move them through the process as quickly and painlessly as possible. We believe that this bill will assist child placing agencies with this part of the licensing requirement.

We also see this as a part of what we hope will be a paperless system that will, in the near future, allow private agencies to submit and check on licensing information without duplicative data entry and the time lost in that process.

To date agencies have not had the ability to receive background information from the national data base. This will provide and important safe guard in cases where families have recently moved to Kansas from another state.

We request the committees support for SB 201

Bruce Linhos Executive Director Children's Alliance of Kansas

# **SENATE BILL No. 202**

#### By Committee on Public Health and Welfare

#### 1-25

AN ACT concerning child care facilities; relating to definitions; amending K.S.A. 65-503 and repealing the existing section.

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

Section 1. K.S.A. 65-503 is hereby amended to read as follows: 65-503. As used in this act:

- (a) "Child placement agency" means a business or service conducted, maintained or operated by a person engaged in finding homes for children by placing or arranging for the placement of such children for adoption or foster care.
- (b) "Child care resource and referral agency" means a business or service conducted, maintained or operated by a person engaged in providing resource and referral services, including information of specific services provided by child care facilities, to assist parents to find child care.
  - (c) (1) "Child care facility" means:
- (A) A facility maintained by a person who has control or custody of one or more children under 16 years of age, unattended by parent or guardian, for the purpose of providing the children with food or lodging, or both, except children in the custody of the secretary of social and rehabilitation services who are subject to the provisions of an adoptive placement agreement or who are related to the person by blood, marriage or legal adoption;
- (B) a children's home, orphanage, maternity home, day care facility or other facility of a type determined by the secretary to require regulation under the provisions of this act;
- (C) a child placement agency or child care resource and referral agency, or a facility maintained by such an agency for the purpose of caring for children under 16 years of age; or
- (D) any receiving or detention home for children under 16 years of age provided or maintained by, or receiving aid from, any city or county or the state.
- (2) "Child care facility" shall not include a family day care home defined in K.S.A. 65-517 and amendments thereto.
  - (d) "Person" means any individual, association, partnership, corpo-

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placed with a prospective adoptive family pursuant

- (e) "Boarding school" means a facility which provides 24-hour care to school age children, provides education as its primary function, and is accredited by an accrediting agency acceptable to the secretary of health and environment.
- 6
- Sec. 2. K.S.A. 65-503 is hereby repealed.Sec. 3. This act shall take effect and be in force from and after its publication in the statute book.



February 5, 2007

The Honorable Jim Barnett, Chairperson Senate Committee on Public Health and Welfare Statehouse, Room 120-S Topeka, Kansas 66612

Dear Senator Barnett:

SUBJECT: Fiscal Note for SB 202 by Senate Committee on Public Health and

Welfare

In accordance with KSA 75-3715a, the following fiscal note concerning SB 202 is respectfully submitted to your committee.

Under current law, operators of licensed child care facilities may provide care for children under 16. Children who are being cared for by relatives are exempt from this statute. SB 202 would also exempt children who are in the custody of the Department of Social and Rehabilitation Services and who live with a family that is close to adopting the child. These families would not be subject to the licensing regulations of the Departments of Social and Rehabilitation Services and Health and Environment.

The Department of Social and Rehabilitation Services and the Department of Health and Environment indicate that there would be no fiscal effect from enactment of SB 202.

Sincerely,

Duane A. Goossen

Director of the Budget

e: Jackie Aubert, SRS



DEPARTMENT OF HEALTH AND ENVIRONMENT Kathleen Sebelius, Governor Roderick L. Bremby, Secretary

www.kdheks.gov

Division of Health

#### Testimony on SB 202

To

Senate Committee on Public Health and Welfare

By Christine Ross-Baze LMSW, Director Child Care Licensing and Registration Program

Kansas Department of Health and Environment

February 14, 2007

Chairman Barnett and members of the Committee on Public Health and Welfare, my name is Christine Ross-Baze and I am the director of the Child Care Licensing and Registration Program at the Kansas Department of Health and Environment. Thank you for the opportunity to appear before you today in support of Senate Bill 202.

SB 202 proposes to amend the definition of a child care facility in order to clarify that individuals wishing to adopt children in the custody of the Kansas Department of Social and Rehabilitation Services, (SRS) and who have signed an adoptive placement agreement, are not subject to licensure by the Kansas Department of Health and Environment.

The Child Care Licensing Act, K.S.A. 65-501 et seq., sets forth requirements for child care facility licensure. When a child under 16 years of age is removed from their parental home and is placed by SRS with a family that is not related to the child by blood, marriage or legal adoption, the Child Care Act requires the family to be licensed as a family foster home.

However, K.S.A. 59-2131 permits the court to order the placement of a child for adoption in an unlicensed family home when the family has been determined to be suitable. K.S.A. 59-2132 requires an adoptive assessment of the family's background and suitability in order to adopt.

The differing statutory requirements governing adoption and child care facility licensure has resulted in unclear direction regarding whether or not families, wishing to adopt children in SRS custody, are required to be licensed as family foster homes.

BUREAU OF CHILD CARE AND HEALTH FACILITIES - CHILD CARE LICENSING & REGISTRATION PROGRAM

BUREAU OF CHILD CARE AND HEALTH FACILITIES - CHILD CARE LICENSING & REGISTRATION PROGRAM

CURTIS STATE OFFICE BUILDING, 1000 SW JACKSON ST., STE. 200, TOPEKA, KS 66612-1270

The proposed language in SB 202 brings these differing statutes into harmony by clearly

Voice 785-296-1270

Fax 785-296-0803

exempting from Child care racility licensure families who wish to adopt children in the custody

of the Secretary of SRS and who have entered into an adoptive placement agreement.

The amendment proposed in SB 202 would result in further streamlining the placement of children into permanent homes. Safety and suitability issues will continue to be addressed through the adoptive assessment and background checks prior to the family signing an adoptive placement agreement and throughout the adoption process.

For these reasons the Department supports the passage of SB 202. I am available to answer any questions you may have.

Robert Drummond TLC for Children and Families, Inc. President



Bruce Linhos Executive Director

Community Agencies Serving Children and Families

212 S.W. 7th Street

Topeka, Kansas 66603

(785) 235-KIDS

fax: (785) 235-8697

e-mail: blinhos@childally.org

Website: www.childally.org

Children's Alliance

Senate Bill 202 Senate Public Health and Welfare February 14, 2007

The Children's Alliance is the association of the private child welfare agencies. Members of our association provide family preservation, foster care, and adoption to children in the custody of the state. Members serve both the youth in JJA and SRS custody. During the course of the year member agencies work with nearly 5,000 children through both adoption and foster care.

Senate Bill 202 provides needed clarification in the definition of child care facilities. This bill brings into line language in various statutes relating to requirement for the licensing of preadoptive families. We believe this clarification will be of assistance to families seeking to adopt and will provide for a greater consistency and understanding among the various agencies involved in the adoptive process.

I ask the committee's support for SB 202.

Bruce Linhos Executive Director Session of 2007

# SENATE BILL No. 284

# By Committee on Public Health and Welfare

2-5

9	AN ACT concerning the radiologic technologists practice act; amending
10	K.S.A. 2006 Supp. 65-7302 and 65-7305 and repealing the existing
11	sections; also repealing K.S.A. 2006 Supp. 65-7306.
12	
13	Be it enacted by the Legislature of the State of Kansas:
14	Section 1. (K.S.A. 2006 Supp. 65-7302 is hereby amended to read as
15	follows: 65-7302. As used in this act:
16	(a) "Board" means the state board of healing arts.)
17	(b)) ("Ionizing radiation" means x-rays, gamma rays, alpha and beta
18	particles, high speed electrons, protons, neutrons and other nuclear par-
19	ticles capable of producing ions directly or indirectly in its passage
20	through matter,
21	(c) "License" means a certificate issued by the board authorizing the
22	licensee to perform radiologic technology procedures on humans for di-
23	agnostic or therapeutic purposes,
24	(d)) ("Licensed practitioner" means a person licensed to practice med-
25	icine and surgery, dentistry, podiatry or chiropractic in this state.)
26	(e) ('Licensure' and 'licensing' mean a method of regulation by
27	which the state grants permission to persons who meet predetermined
28	qualifications to engage in a health related occupation or profession.
29	(f) "Nuclear medicine technologist" means a person who uses radio
30	pharmaceutical agents on humans for diagnostic or therapeutic purposes.
31	(g) "Nuclear medicine technology" means the use of radio nuclides
32	on human beings for diagnostic or therapeutic purposes.
33	(h)) "Radiation therapist" means a person who applies radiation to
34	humans for therapeutic purposes.)
35 36	(i) "Radiation therapy" means the use of any radiation procedure or
37	article intended for the cure, mitigation or prevention of disease in
38	(humans.)
39	(j)) "Radiographer" means a person who applies radiation to humans) for diagnostic purposes.
40	((k)) "Radiography" means the use of ionizing radiation on human be-:
41	(ings for diagnostic purposes.)
42	(I) ('Radiologic technologist' means any person who is a radiographer,
43	radiation therapist or nuclear medicine technologist.

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(m) "Radiologic technology" means the use of radioactive substance or equipment emitting or detecting ionizing radiation on humans for diagnostic or therapeutic purposes upon prescription of a licensed practitioner and the administration of medications within the scope of training of the radiologic technologist as allowed by the board. The term includes the practice of radiography, nuclear medicine technology and radiation therapy, but does not include echocardiography, diagnostic sonography and magnetic resonance imaging.

(n) This section shall take effect on and after July 1, 2005.

Sec. 2.) K.S.A. 2006 Supp. 65-7305 is hereby amended to read as follows: 65-7305. (a) An applicant for licensure as a radiologic technologist shall file an application, on forms provided by the board, showing to the satisfaction of the board that the applicant meets the following requirements:

(1) At the time of the application is at least 18 years of age;

- (2) has successfully completed a four-year course of study in a secondary school approved by the state board of education, passed an approved equivalency test or graduated from a secondary school outside Kansas having comparable approval by the state board of education;
- (3) has satisfactorily completed a course of study in radiography, radiation therapy or nuclear medicine technology which is approved by the board and which contains a curriculum no less stringent than the standards of existing organizations which approve radiologic technology programs;
- (4) except as *otherwise* provided in K.S.A. 2006 Supp. 65-7306, and amendments thereto this act, has successfully passed a license examination approved by the board; and
  - (5) has paid all fees required for licensure prescribed in this act.
- (b) The board may issue a temporary license to an applicant seeking licensure as a radiologic technologist when such applicant meets the requirements for licensure or meets all the requirements for licensure except examination and pays to the board the temporary license fee as required under K.S.A. 2006 Supp. 65-7313, and amendments thereto. Such temporary license shall expire 180 days from the date of issue or on the date that the board approves the application for licensure, whichever occurs first. No more than one such temporary license shall be permitted to any one person.
- (c) The board may accept, in lieu of its own licensure examination, a current certificate by the American registry of radiologic technologists, nuclear medicine technologist certification board or other recognized national voluntary credentialing bodies, which the board finds was issued on the basis of an examination which meets standards at least as stringent as those established by the board.

- (d) The board may waive the examination or education requirements and grant licensure to any applicant: (1) Who presents proof of current licensure as a radiologic technologist in another state, the District of Columbia or territory of the United States which requires standards for licensure determined by the board to be equivalent to the requirements under this act; and (2) who has, at the time of application, a current valid certificate by the American registry of radiologic technologists, nuclear medicine technology certification board or other recognized national voluntary credentialing bodies, which the board finds was issued on the basis of an examination which meets standards at least as stringent as those established by the board.
- (e) A person whose license has been revoked may make written application to the board requesting reinstatement of the license in a manner prescribed by the board, which application shall be accompanied by the fee provided for in K.S.A. 2006 Supp. 65-7308, and amendments thereto.
  - (f) This section shall take effect on and after July 1, 2005.

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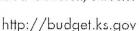
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- Sec. 3. K.S.A. 2006 Supp. 65-7302, 65-7305 and 65-7306 are hereby repealed.
- Sec. 4. This act shall take effect and be in force from and after its publication in the statute book.

And renumber the remaining sections accordingly





February 13, 2007

The Honorable Jim Barnett, Chairperson Senate Committee on Public Health and Welfare Statehouse, Room 120-S Topeka, Kansas 66612

Dear Senator Barnett:

SUBJECT: Fiscal Note for SB 2184 by Senate Committee on Public Health and Welfare

In accordance with KSA 75-3715a, the following fiscal note concerning SB 284 is respectfully submitted to your committee.

SB 284 would make three changes to the Radiologic Technologist Practice Act. Radiologic technologists are licensed under the authority of the Board of Healing Arts. The bill would:

- 1. Allow technologists to administer medications, as approved by the Board of Healing Arts;
- 2. Waive the examination or education requirements and grant licensure to any applicant who holds a valid certificate from the American Registry of Radiologic Technologists, the Nuclear Medicine Technology Certification Board, or another recognized national credentialing body; and,
- 3. Delete the "grandfather" provisions that allow the Board to waive education and examination requirements for persons who practiced radiologic technology prior to July 1, 2005 but who have not passed the examination and who have not completed the education requirements.

The Board of Healing Arts indicates that the passage of SB 284 would not have a fiscal effect on the agency. Those radiologic technologists who have been "grandfathered" may experience additional costs to complete the requirements for licensing.

900 S.W. Jackson Street, Room 504-N, Topeka, KS 66612 • (785) 296-2436 • Fax<sub>N</sub> (785) 296-0231

Sincerely,

Duane A. Goossen Director of the Budget

Duane a Dossen

Aaron Dunkel, KDHE

cc: Cathy Brown, Healing Arts

e-mail: duanc.goossen@budget.ks.gov Severte Public Head Attachment #8 February 15, 2007

# KANSAS BOARD OF HEALING ARTS

LAWRENCE T. BUENING, JR. EXECUTIVE DIRECTOR



KATHLEEN SEBELIUS GOVERNOR

# **MEMORANDUM**

TO:

Senate Public Health and Welfare Committee

FROM:

Lawrence T. Buening, Jr.

**Executive Director** 

DATE:

February 13, 2007

RE:

Senate Bill No. 284

Thank you for the opportunity to appear before you on behalf of the State Board of Healing Arts in support of S.B. No. 284. The amendments that are made by this bill have been recommended by the Radiologic Technology Council and were presented to and approved by the Board as a whole.

In June, several individuals inquired whether the Board had any guidelines for flushing IVs with normal saline. After reviewing the statutes, it did not appear that flushing IV lines with normal saline was within the definition of "radiologic technology" as set forth in K.S.A. 2006 Supp. 65-7302(m) since normal saline is not a radioactive substance. The Radiologic Technology Council met on July 28 and recommended that the statutory language be amended to authorize radiologic technologists to flush IVs and to administer contrast dyes. The Council also recommended changes that would repeal the "grandfather" provisions that have been in effect since July 1, 2004. S.B. No. 284 was presented to and approved by the Board as a whole last Friday, February 9.

Section 1 of the bill amends K.S.A. 65-7302(m) to allow radiologic technologists to administer medications as allowed by the Board. Section 2 adds a new subsection (d)(2) to K.S.A. 2006 Supp. 65-7305 and would allow the Board to waive examination and education requirements for individuals who have a current and valid certificate issued by the ARRT or the NMTCB. Section 3 repeals K.S.A. 2006 Supp. 65-7306 which contains the current grandfather provisions for individuals who had practiced radiologic technology prior to July 1, 2005 but had neither formal education nor had passed the examination required for licensure. As the Radiologic Technologists Practice Act has now been in existence since July 1, 2004, the Board rarely receives applications from individuals based only on their work experience prior to July 1, 2005.

I would be happy to respond to any questions.

MEMBERS OF THE BOARD:

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BETTY MCBRIDE., Public Member, VICE-PRESIDENT Columbus

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5845 SW 29<sup>th</sup> Street, Topeka, KS 66614-2462 Phone: (785) 273-1441 Fax: (785) 273-9243

Ronald R. Hein Attorney-at-Law Email: rhein@heinlaw.com

Testimony re: SB 284
Senate Public Health and Welfare Committee
Presented by Ronald R. Hein
on behalf of
Kansas Society of Radiologic Technologists
February 14, 2007

Mr. Chairman, Members of the Committee:

My name is Ron Hein, and I am legislative counsel for the Kansas Society of Radiologic Technologists. The KSRT is the professional association for radiologic technologists in Kansas.

KSRT supports the passage of SB 284. This bill amends the scope of practice for radiologic technologists to permit rad techs to administer medications, which are within their scope of training and competence, and which have been approved by the Board of Healing Arts (BOHA). This bill was originally brought to our attention by the BOHA, and was prompted by a request for guidance from the BOHA on whether a rad tech can flush an IV. When that question was proposed to the Board of Healing Arts, Larry Buening, Executive Director of the Board, realized that the scope of practice for rad techs did not address the issue of administration of medicines.

We view this change as simply technical in nature, and this bill is not designed to expand the actual scope of practice for rad techs, nor to permit them to perform any functions, or to utilize any medications, which are not already permitted within the scope of practice that they are currently performing. However, since scopes of practice for all healthcare providers other than physicians, are narrow, and prescribe what practitioners can do, it is necessary to make this change to the statute.

The second amendment repeals the grandfather clause which was necessary when rad techs were first licensed, and is, again, simply a technical clean-up to the statute. This amendment necessitates a change in K.S.A. 65-7305 to incorporate language which is currently in K.S.A. 65-7306, which will be repealed. The language which is inserted into K.S.A. 65-7305(d), includes language that basically continues the grandfathering of persons who have AART certification who may come to Kansas from other states.

We have talked with other groups that are interested in this legislation including the KMS. We urge the committee to report SB284 with the recommendation that it be passed.

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

# KANSAS BOARD OF HEALING ARTS

LAWRENCE T. BUENING, JR. EXECUTIVE DIRECTOR

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KATHLEEN SEBELIUS GOVERNOR

February 15, 2007

Jim Barnett, M.D., State Senator Chair, Senate Public Health and Welfare Committee Room 120-S, State Capitol Topeka, KS 66612

Re: S.B. No. 284

Dear Senator Barnett:

Following the hearing on S.B. No. 284, interested parties met regarding the proposed amendments to K.S.A. 2006 Supp. 65-7302(m) contained in Section 1 of the bill. It was agreed by all involved in the discussions that no amendments to K.S.A. 2006 Supp. 65-7302(m) are necessary at this time. Therefore, Section 1 of the bill can be deleted in its entirety and Section 3 amended to delete K.S.A. 65-7302 as being repealed. Ms. Folmsbee is aware of this agreement and has prepared a balloon amendment.

As stated in my written testimony, the Board has received several inquiries concerning guidelines for flushing IVs with normal saline by radiologic technologists. The Radiologic Technology Council met and indicated certain radiologic technologists intravenously administer numerous pharmacologic agents in addition to normal saline as part of their professional practice. So, the amendments in Section 1 were proposed to include administration of medications with the definition of "radiologic technology".

While the administration of medications is not specifically allowed under the Radiologic Technologists Practice Act, it does not translate that radiologic technologists are prohibited from administering drugs. All parties agree that radiologic technologists, in the course of their professional duties, only administer drugs upon the order of a licensed practitioner. Based on current and long-standing statutory and case law, radiologic technologists may administer drugs in the course of their professional practice as long as those drugs are administered under the supervision or by order of or referral from a licensed practitioner. Thus, a statutory amendment to specifically include the administration of medications as part of the professional practice of radiologic technologists is not necessary.

Very truly yours,

Lawrence T. Buening, Jr.

**Executive Director** 

MEMBERS OF THE BOARD:

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235 S. Topeka Boulevard, Topeka, Kansas 66603-3068

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

February 15, 2007





February 12, 2007

The Honorable Jim Barnett, Chairperson Senate Committee on Public Health and Welfare Statehouse, Room 120-S Topeka, Kansas 66612

Dear Senator Barnett:

SUBJECT: Fiscal Note for SB 229 by Senate Committee on Public Health and

Welfare

In accordance with KSA 75-3715a, the following fiscal note concerning SB 229 is respectfully submitted to your committee.

SB 229 would prohibit a pharmacy, electronic transmission intermediary, insurance company, or pharmacy benefits manager (PBM) from using or selling prescription records for any commercial purpose. The bill would make the commercial use of pharmacy records a violation of the Pharmacy Act. The bill would also require clearinghouses to report to the Department of Social and Rehabilitation Services (SRS) annually the number of people in Kansas who qualify for any manufacturer or government prescription assistance program and the number of people who were served during the calendar year. Individual pharmaceutical companies could report on their patient assistance programs, but SRS would be required to combine all information from all sources and report aggregate information to the public.

Estimated State Fiscal Effect					
	FY 2007 SGF	FY 2007 All Funds	FY 2008 SGF	FY 2008 All Funds	
Revenue					
Expenditure				\$81,000	
FTE Pos.				1.00	

The Board of Pharmacy states that it would have the responsibility for investigating and administratively prosecuting violators. Although the number of violations cannot be predicted, the Board states that an additional inspector would be needed. The agency estimates salary

The Honorable Jim Barnett, Chairperson February 12, 2007 Page 2—229

expenditures for the new inspector at \$65,000 per year, and an additional agency vehicle for the inspector would cost approximately \$16,000. The agency also states that it would have additional legal and court reporter fees, but an estimate cannot be made without the number of violations. If the agency adds staff, it may also have to consider the need for additional office space.

The fiscal effect of this bill is difficult to estimate because it creates new administrative responsibilities. The fiscal estimate provided is based on the agency's best judgment of the effect that the bill would have on its operations. However, the lack of reliable information and the absence of past experience suggest that the fiscal effect presented here cannot be more than a general indication of the cost based on a thoughtful consideration of the factors and assumptions involved.

SRS states that the reporting requirement in SB 229 would have no fiscal effect on the agency.

Sincerely,

Duane A. Goossen Director of the Budget

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cc: Debra Billingsley, Pharmacy
Jackie Aubert, SRS
John Campbell, Insurance Department
Scott Brunner, KHPA



Thursday, February 15, 2007

Senator Jim Barnett Chairman, Senate Public Health & Welfare Committee

Good Morning Chairman Barnett and members of the Senate Public Health and Welfare Committee. Thank you for providing me the opportunity to speak before the committee about Senate Bill 229. I am David Wilson, Volunteer State President for AARP Kansas. On behalf of AARP Kansas' nearly 360,000 members we support Senate Bill 229. This piece of legislation will help maintain the privacy between a doctor and patient and enable doctors not to be targeted by drug manufacturers to increase sales without regard to efficacy.

Generally, pharmaceutical detailing is a marketing strategy where individual pharmaceutical sales representatives, also known as "detailers," meet with physicians to promote new medications. The marketing technique is used by companies to "educate" prescribing health professionals (physicians, physician assistants, psychiatrists, nurse practitioners and several others) about the benefits of specific products. This practice is predominantly used by brand name drug manufacturers.

According to the Wall Street Journal, there is no way to determine exactly how many drug detailers are in the United States however, it is estimated that industry-wide, nearly 100,000 pharmaceutical representatives are employed in the U.S.1 With over 630,000 practicing physicians today,<sup>2</sup> that averages out to 1 representative per 6-7 physicians. Detailing

555 S. Kansas Avenue, Suite 201 | Topeka, KS 66603 | toll-free 866-448-3619 | 785-232-8259 fax | toll-free 877-434-7598 TTY Erik D. Olsen, President | William D. Novelli, Chief Executive Officer | www.aarp.org/ks Sencete Public Health and Welter P Attach ment #//

February 15,2007

<sup>&</sup>lt;sup>1</sup> "To Sell Their Drugs, Companies Increasingly Rely on Doctors," The Wall Street Journal, p. A1-2, July 15, 2005

American Medical Association Physician Masterfile, Dec. 2000, accessed at http://www.amaassn.org

accounted for more than \$5.3 billion in industry activities in 2004. In a recent report by Lehman Brothers, a single detailer can generate around \$1.9 million in increased sales.

As part of the drug industry's marketing to doctors, the industry closely monitors the prescribing patterns. Highly detailed data on each doctor is continuously channeled to industry representatives. The practice is commonly known as physician profiling. This allows a drug company to see how often their drugs or a competitor's drug is being prescribed. It also provides a clear picture to determine whether informal meetings with company representatives, gifts and other incentives are effective in encouraging doctors to prescribe the medication more often.

I encourage you read several of the articles I provided. The *Boston Globe* article explains how "prescriber profiling" works and how effective it is in increasing the sales of high cost, brand name drugs. Several articles have surfaced on this practice over the last few months including one in Nebraska two weeks ago.

A New York Times article from January 28, 2006 quotes a district manager's email to pharmaceutical sales staff stating: "Our goal is 50 or more scripts per week for each territory.... If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!"

AARP believes that data on which medications doctors prescribe for their patients should be confidential. This information should not be sold to the drug industry for the sole purpose of increasing sales without regard to efficacy. The legislation allows for exceptions "for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law." These safeguards will insure that provider level data is used properly to ensure the patient's safety and overall health.

Without proper controls, the industry will continue to use this data to increase the sales of higher price brand name drugs, even when lower costs medications are just as safe and effective.

Finally, there are no silver bullets or single answers in addressing the high cost of prescription medications. Restricting pharmaceutical companies from using this data will reduce the direct access to physician prescribing patterns. While drug sales representative will still be able to say anything they want to doctors about their products, they will be unable to create the type of pressure that is possible only when the sales representative has access to data showing whether the doctor is complying with their recommendation. Undoubtedly, pharmaceutical sales representatives will still visit offices, bestow gifts, and seek to persuade a doctor to prescribe the favored brand-name drug in greater quantities. We support the state in seeking to immunize doctors from the most insidious form of pressure exerted by pharmaceutical sales representatives that is only possible with doctor-specific prescription data.

Thank you for your consideration of this request and your support of SB 229. I will stand for questions.

David Wilson.

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## New Treatment: To Sell Their Drugs, Companies Increasingly Rely on Doctors

For \$750 and Up, Physicians Tell Peers About Products Talks Called Educational Dr. Pitts's Busy Speaking Tour

By Scott Hensley and Barbara Martinez, The Wall Street Journal, 1945 words Jul 15, 2005

#### **Document Text**

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NEW YORK -- On a recent Wednesday evening, neurologist Lawrence Newman spoke to a dozen doctors in a private alcove off the soaring dining room of Guastavino's and made the case that migraine headaches are seriously underdiagnosed.

Migraine treatment "should be bread and butter for primary-care doctors," he told attendees at the midtown Manhattan restaurant. While patients might say they're having a sinus headache, there's a good chance it's actually a migraine and can be treated with a migraine drug, Dr. Newman said.

It was a message friendly to migraine-drug makers, and no wonder: The sponsor of the talk was GlaxoSmithKline PLC, maker of the best-selling migraine pill Imitrex. Glaxo picked up the tab for dinner, paid Dr. Newman a fee, supplied some of his slides, and scattered Imitrex notepads on the table.

Drug makers have seized upon an effective tool for getting their message across to doctors: other doctors.

Across the U.S., thousands of doctors such as Dr. Newman, an associate professor of clinical neurology at Albert Einstein College of Medicine, have signed up as part-time lecturers for drug companies. At small meetings, often over lunch or dinner, these physician- pitchmen tell their peers about diseases and the drugs to treat them, often pocketing \$750 or more from the sponsor. Dr. Newman declined to discuss his fee.

In 2004, 237,000 meetings and talks sponsored by pharmaceutical companies featured doctors as speakers, compared with 134,000 meetings led by company sales representatives, according to market researcher Verispan LLC of Yardley, Pa. In 1998, events featuring sales reps and physicians were about equal at just over 60,000 each, Verispan says.

The growing use of talks by doctors comes as drug makers face criticism over other sales tactics. Direct-to-consumer advertising has drawn fire and some companies are voluntarily restricting the practice. The industry's nearly 100,000 salespeople in the U.S. are facing resistance from doctors who complain about being besieged in their offices. Drug maker Wyeth plans to cut its main sales force, which calls on primary-care doctors, by as much as 30% this year.

Companies formerly curried favor with doctors by taking them on free golf outings or filling up their cars with a tank of gas in exchange for listening to a sales pitch. But a voluntary marketing code adopted by the largest drug companies three years ago barred such inducements.

Hiring a doctor as a speaker and providing a free meal for the attendees is still acceptable -- and, data suggest, highly effective. An internal study done by Merck & Co. several years ago calculated the "return on investment" from doctor-led discussion groups was almost double the return on meetings led by the company's own sales force.

Drug makers and the doctors they sponsor say the talks are educational. Dr. Newman, the speaker at the Guastavino's dinner, said he refuses to give talks centered on a single drug or those he considers promotional.

When one doctor at the dinner interrupted with a question and said the talk was really about Imitrex, Dr. Newman smiled and disagreed. He said doctors should choose a medicine to match their patients' condition, then rattled off the generic and brand names of Imitrex and six rival drugs.

Dr. Newman said he gives about three industry-sponsored talks a month, usually during the day rather than at dinner. He said he tells pharmaceutical companies, "Your job is to sell the drug and my job is to educate."

Mary Anne Rhyne, a spokeswoman for Glaxo, the second-largest drug maker, says: "The purpose of these events is to share information with health-care professionals about disease, diagnosis and treatment, including the use of our medicines." Glaxo makes no secret of its sponsorship of the events: Its sales representatives give out written invitations with the Glaxo name on them.

Those who question the talks say drug companies are bombarding doctors with one-sided information through the seemingly neutral medium of independent speakers who often have prestigious affiliations. "An awful lot of the doctors in the audience are naive about the fact that these are really sales talks," says Jerry Avorn, a professor of medicine at Harvard Medical School and author of a recent book that criticized drug companies' marketing.

Also, speakers who make thousands of dollars in fees from drug companies aren't required to disclose their side job to patients, although they are expected to disclose their ties in scientific papers.

Some critics see a problem not only with talks such as the one Dr. Newman gave but also with the sessions at which companies train their doctor-speakers. Steven Bernstein, an internist at the University of Michigan Health System in Ann Arbor, thinks drug makers may bring more doctors to speaker training than they need because the training is itself excellent advertising. Doctors are invited, says Dr. Bernstein, to "try to convince them to utilize these products, and second, to use them as a marketing arm for the firm's products to their colleagues."

The drug industry's voluntary marketing code says companies should train speakers and consultants only if they intend to use them. The code responds to criticism of a practice popular in the 1990s under which companies would give doctors an all-expenses-paid trip in exchange for a brief "consulting" opinion about the company's drug. Scott Lassman, assistant general counsel at PhRMA, the drug trade group, says he believes companies are observing the code.

Some doctors have earned considerable sums from their moonlighting as speakers. Subir Roy, a gynecologist who teaches at the University of Southern California, received \$61,250 in fees and an additional \$11,117 for expenses in 2002 from Wyeth, according to a list compiled by Wyeth and submitted by Dr. Roy to the U.S. District Court in Phoenix. During that year he spoke 53 times about Prempro and Premarin, Wyeth's drugs to ease the symptoms of menopause. The drugs were in the news that year because a big federal study suggested Prempro could increase the risk of heart attack and stroke in women.

The data about Dr. Roy emerged after a former Wyeth sales representative filed suit against the company, saying it failed to stop Dr. Roy from making unwelcome sexual advances on her. Dr. Roy denies doing anything improper. The former sales rep, Anissa Groves, alleges that Wyeth fired her because it didn't want to jeopardize its ties with Dr. Roy. A Wyeth spokesman, Chris Garland, said the company treated Ms. Groves appropriately throughout her employment and that her departure, nearly two years after her allegations about Dr. Roy, was unrelated to her complaint.

In a December 2004 deposition, Dr. Roy said he no longer spoke for Wyeth but gave talks for several other drug makers in 2004 including Pfizer Inc., Merck, Johnson & Johnson and Novartis AG. He said then that he maintains no private practice and relies on speaking to supplement his salary from USC.

In an interview, Dr. Roy says, "My interest is in dissemination of accurate information." Wyeth's Mr. Garland says talks by speakers such as Dr. Roy are intended to "educate health-care providers with information about Wyeth products" and the diseases they treat.

David Pitts, an internist in Grants, N.M., says he speaks about once a month on behalf of pharmaceutical companies, less than he used to. "You have to figure all your time traveling and going through airports. Once you average that in, it can end up being not nearly as lucrative as you might think," Dr. Pitts says.

Dr. Pitts was paid by Merck to speak at 134 events in 1999 related to Zocor, Merck's anticholesterol drug, according to an internal Merck document titled "Speaker Utilization as of 12/29/99." Other Merck documents say the maximum payments for the types of talks Dr. Pitts gave ranged from \$1,500 to \$2,000, suggesting he could have made \$200,000 or more from Merck in that year. Dr. Pitts declined to estimate his income from Merck but says, "I was a popular speaker and I had trouble saying no when reps asked."

In a Merck slide presentation dated December 2001, two Merck employees observed that doctors who attended lectures or more intimate roundtable-type discussions were much more likely to increase their prescribing of certain medications than those who spent time with a Merck sales representative.

According to the document, doctors who attended a lecture by another doctor wrote an additional \$623.55 worth of prescriptions for the painkiller Vioxx over a 12-month period compared with doctors who didn't attend. Doctors who participated in the more intimate discussions wrote an additional \$717.53 worth of prescriptions for Vioxx, which Merck pulled from the market last year over concerns about cardiovascular side effects. That compared to an increase of only \$165.87 in Vioxx prescriptions by doctors who attended a meeting with a salesperson.

After factoring in the extra cost of hiring a doctor to speak, Merck calculated that the "return on investment" of the doctor-led discussion group was 3.66 times the investment, versus 1.96 times for a meeting with a sales representative. The document concluded that peer discussion groups led by doctors "provide the best return on investment for A-rated physicians," an internal term for doctors who write a lot of prescriptions. "A-rated physicians are not responsive" to meetings led by sales representatives, it said.

Merck declined to discuss the document's conclusions but in a written statement the company says its policy has always been to supply "accurate and balanced" information to doctors. "One way Merck provides such information is through physician speakers...," the statement says.

While the total number of company-sponsored doctor talks is rising, both Merck and Wyeth say they have taken steps to rely less extensively on individual speakers. Doctors speaking on Merck's behalf now do so an average of five to 10 times a year, the company says. At Wyeth, speakers can't appear more than 25 times or earn more than \$25,000 giving talks each year.

Companies say they're putting in caps to avoid the appearance that they're trying to influence any individual doctor's choice of drugs with outsized speaking fees. Several cases brought by the U.S. government against drug companies in the past have involved allegations that companies paid doctors in exchange for prescribing drugs.

Meanwhile, companies are stepping up training of new speakers. Pfizer trained hundreds of speakers last year to help the company launch Caduet, a single pill containing blood-pressure reducer Norvasc and cholesterol-lowering Lipitor.

One of those trained was Dr. Bernstein of the University of Michigan Health System. He is active in efforts to counter the pitches of drug- company salespeople by telling doctors and pharmacists at his organization about generic drugs and other alternatives. He says he accepted an invitation to be trained to talk about Caduet in order to learn more about his opponents' strategy. About 185 doctors attended the session at the Omni Mandalay Hotel in Dallas in April 2004.

For attending a welcome dinner and reception on Friday night, and 51/2 hours of training plus lunch the next day, Dr. Bernstein earned a \$750 fee. Under the terms of the invitation, he agreed to give at least one talk afterward, for which he would have been paid another \$750. Pfizer provided him with a deck of PowerPoint slides for presentations. A Pfizer sales rep was supposed to make arrangements for the talk.

But Dr. Bernstein said he was never approached to fulfill that part of the bargain, fueling his suspicion that companies may be training more speakers than they need. Pfizer confirms that it is training more speakers than it used to, but a spokeswoman, Mariann Caprino, says: "The majority of the speakers that we have trained are used and used often." She adds: "We would never knowingly train them and not use them."

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# DRUG COMPANIES' SECRET REPORTS OUTRAGE DOCTORS

BYLINE: By Liz Kowalczyk, Globe Staff

Several months ago, a pharmaceutical company salesman told Dr. Mario Motta something that surprised him. The salesman, who had scheduled a 15-minute appointment with Motta, said he knew that the doctor had been prescribing a competitor's cardiac drugs - and he wanted Motta to switch.

Motta had never discussed his personal prescribing habits with the salesman. "I said, 'How would you know that?' " Motta recalled. "I couldn't get it out of him, so I told him to leave."

Drug makers, in a level of detail unknown to many physicians, are spending millions of dollars to develop secret reports about individual doctors and their patients, according to consultants to the drug companies.

Most physicians know drug companies collect some information about which medications they prescribe. But they are often surprised by the depth of detail pharmaceutical makers now are buying about almost every US physician, mostly from large pharmacy chains. The details include whether doctors are switching specific patients from one drug to a competitor within days of it happening, and whether they treat many poor patients and may want free samples.

With many doctors now holding sales representatives to strict time limits when they visit, these "prescriber profiles" allow reps to tailor their pitches to individual physicians. They are an increasingly important tool in drug company marketing to doctors, which accounts for the largest portion, \$16 billion, of the \$19 billion that pharmaceutical companies spent on marketing in 2001, according to IMS Health, a Connecticut-based compmany that collects prescriber data.

"Average sales calls are shorter, and physicians are seeing fewer sales reps," said E.M. "Mick" Kolassa, a professor at the University of Mississippi and managing partner of Medical Marketing Economics, which provides consulting services to drug companies. "Because of this, the sales call has become a more precious commodity and companies need to make sure they're putting their resources in the right place."

But even though patient names are removed from the data, some doctors believe these

secret reports - which they say sales reps almost never discuss openly with them - are an unwelcome intrusion into the doctor-patient relationship. Doctors worry that the reports allow sales reps to push expensive drugs more effectively in a health care system that already is struggling with soaring costs.

"The amount of information they have about us and our prescribing is staggering," said Dr. Mark Rohrer, an internist and geriatrician at St. Elizabeth's Medical Center in Boston. "The important thing is how it's used. If it's used by a rep to pressure me to provide a different drug than the one I'm prescribing, especially if there's a generic alternative, I don't think that's right."

Several drug makers, including Eli Lilly and Wyeth, and the Pharmaceutical Research and Manufacturers of America, the industry trade group, would not comment on prescriber profiling.

Michael Barnes, vice president of business intelligence solutions at Dendrite International Inc., which provides prescription data to drug companies, said the data are used to promote safety.

For instance, the Food and Drug Administration buys Dendrite's prescribing data, which allows the agency to monitor cases in which large groups of patients are taking drugs that could have dangerous interactions, he said. The agency can then direct the company to educate doctors about the potential harm.

Prescriber profiles, albeit in a more rudimentary form, are a key element in the whistle-blower lawsuit David Franklin filed against his former employer, Parke-Davis, now part of Pfizer, alleging illegal and off-label marketing of the company's top-selling epilepsy drug, Neurontin. Federal investigators are in settlement talks with Pfizer, which declines to discuss the case.

Franklin, who worked as a medical liaison for Parke-Davis from April to July 1996, said his supervisors would provide him with a doctor's prescribing record for the previous month before he went on a sales call.

A month later, they would send him the physician's new prescriptions, so he could see if the information he gave to the doctor led him to prescribe more Neurontin or other Parke-Davis drugs. Now sales reps can see within days if a doctor is responding to a pitch, he said.

If a doctor was prescribing a competitor's product, Franklin knew that his presentation should focus on undermining that product, he said.

Sales people also reviewed doctors' prescribing habits to determine who was loyal and should receive trips and gifts. The industry has since put in place voluntary guidelines discouraging lavish trips and gifts.

"The doctors it didn't work on didn't get the gifts anymore because it was throwing money away," he said. "Your physician would be stunned to find out what pharmaceutical reps know about them before they walk into the office. We were trained in how to use this information without letting the doctor know we had it. It was absolutely imperative that you never referred to the report."

Documents recently unsealed in Franklin's lawsuit in US District Court in Boston also show Parke-Davis conducted prescriber profiling to determine whether dinner meetings, lectures, and teleconferences persuaded physicians who attended to prescribe more Parke-Davis drugs. Sometimes it worked, according to the company's analyses, and sometimes it didn't.

Since the mid-1990s, drug companies have hired outside firms that purchase data on physicians from pharmacies and used the information in marketing. It's legal in the United States as long as patients are not identified. However, the Canadian province of British Columbia outlawed the practice in 1996. But in the last two years, the data have gotten more sophisticated.

"What's really changed in the last year or two is the speed at which they can get it," Kolassa said.

Companies that buy data and sell it to drug makers are creating and advertising new products.

Verispan, based in Pennsylvania, promises on its website that a new product called Market Mover will deliver changes in doctor prescribing behavior four days after the close of the week. It's "the fastest available indicator of changes in individual prescribing behavior," the company says. The company now sends these prescriber "alerts" directly to the sales rep's laptop. Verispan executives would not discuss prescriber profiling.

Companies such as IMS Health purchased computer records or tap directly into the pharmacy computer and extract information on the 3 billion prescriptions US pharmacies fill annually, according to industry specialists. They combine this information with biographies on nearly 850,000 physicians compiled by the American Medical Association, which earns \$30 million annually licensing detailed reports on physicians, including where they went to medical school, their fax numbers, and their specialties. About 20,000 doctors have opted to be removed from the list.

AMA past president Dr. Richard Corlin said the list serves an important safety function: It allows drug companies to immediately alert doctors to a problem with a drug or change in how a medication should be used. But after some of its own members began criticizing the AMA for providing the list for marketing purposes, the organization a year ago adopted guidelines for drug companies that license the data, saying they should not use it to pressure doctors to change drugs.

AMA officials said they would consider suspending a licensing agreement with any drug

company that violated these guidelines, but that they haven't received any complaints from doctors to that effect.

Verispan, IMS, and other companies also now buy data not just on individual doctors, but on individual patients and the medications they're taking. Executives at CVS and Walgreens, as well as Dendrite's Barnes, said pharmacies remove patient names and identifying details from the data and assign each person a non-traceable number. But the data include information such as a patient's insurance provider, all the drugs a patient takes, and the doses. Pharmacies would not say how much they charge for the data.

Barnes said the patient data are crucial because they follow individual patients, so drug companies can see whether doctors are merely placing new patients on a competitor's drug or whether they're actually switching existing patients off one drug and onto another - a greater cause for alarm.

If a drug company, for example, finds doctors are switching patients off of its cholesterol-lowering drug after they don't respond to a 40-milligram dose, the company can direct its sales force to focus on telling doctors to increase the dose.

With doctor-specific data, drug companies could tell only if a doctor was writing more prescriptions for a particular medication, but nothing about who was getting the drugs. The patient-specific data allow drug companies to see changes in physician prescribing behavior eight months sooner, "which could save tens of millions of dollars for the company," Barnes said.

Barnes said the more advanced data also are used to promote safety. The FDA buys Dendrite's prescribing data, for example; this allows the agency to monitor cases in which large groups of patients are taking drugs that could have dangerous interactions. The agency can then direct the company to educate doctors about the potential harm.

But even when it comes to pure marketing, Kolassa said he doesn't believe prescriber profiling is unethical. "It's done throughout business. Frito-Lay knows a lot more about you than Merck knows about individual physicians. They know whether you bought beer or Diet Coke with your corn chips. Besides, physicians can always tell sales reps to take a hike."

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#### Bill seeks to limit drug companies influence

By NANCY HICKS / Lincoln Journal Star Thursday, Feb 08, 2007 - 12:07:14 am CST

Omaha physician Roger Kobayashi knows the seductive practices of drug reps, who try to win converts to their company's drugs with the gifts they give.

Through the years, he's been the "recipient of pharmaceutical attention," including free meals, concerts at Carnegie Hall and research grants.

Pharmaceutical companies have paid him to speak in Europe and Hawaii. They've taken him golfing, to sporting events. He's even had "dynamic, blue-eyed blondes cozy up to a wrinkled old prune like me," the doctor said in written testimony to the Legislature's Health and Human Services.

The gifts have gotten much more expensive than the leather doctor bag filled with equipment that Eli Lilly wanted to give all incoming freshman when he started medical school 37 years ago.

Kobayashi no longer sees drug reps. He has refused to give lectures for drug companies and has stopped doing "research" that was conducted primarily to position a company's product.

But it hasn't been easy. Because drug reps are able to get information about physician's prescribing habits, he is still the target of pharmaceutical salespeople who want to change his prescribing habits.

Kobayashi says he learned about the specifics of this practice years ago when a company accidentally sent him its "dossier" on a group of physicians' prescribing practices and how influential these physicians were.

The Omaha doctor, an immunologist and allergist, spoke in support of a bill (LB451) that would prohibit pharmacies from selling data to drug companies showing what doctors were prescribing.

Kobayashi described the practice as "abuse of physician confidentiality and privacy," and said it is used as a tool for companies to target doctors who are not prescribing their drugs. It has been used to influence doctors to prescribe medicines that patients might not need, he told the committee.

But much of his testimony could have been used to support another bill (LB675) that would require pharmaceutical companies to report all gifts above \$25 to doctors and hospitals.

Both bills were supported by the AARP of Nebraska as ways to curb rising drug costs. Both were opposed by the Pharmaceutical Research and Manufacturers of America, representing the pharmaceutical industry.

The information-gathering measure would allow senators to find out how much drug companies spend to wine and dine the state's doctors, trying to influence their prescription habits.

It's a lot of money if Nebraska is similar to Vermont, which has gathered this kind of data for several years. Pharmaceutical companies spent more than \$1.45 million in 2005 on the top 100 recipients in Vermont. The companies spent more than \$2.1 million in the state that

year, including \$204,800 on food, according to information provided by AARP Nebraska.

But company reps are an important educational link to doctors, according to an industry lobbyist. They assure that physicians get the latest, most accurate information, said Tara Ryan, representing the Pharmaceutical Research and Manufacturers of America. The industry also has a voluntary code guiding ethical relationships between industry reps and doctors, Ryan said.

The data on what doctors are prescribing is necessary so companies can target safety messages to physicians who are most likely are using specific drugs, she said.

The data can also be required under FDA risk management plans where companies are required to monitor prescribing practices for specific drugs, she said in opposition to the bill banning release of physician prescription data.

Ryan also pointed out that physicians can ask that their prescription information not be given to pharmaceutical companies under an opt-out program through the American Medical Association. "A mechanism is in place for doctors who don't want to be inundated with calls," she said.

Reach Nancy Hicks at 473-7250 or nhicks@journalstar.com.

January 28, 2006

## Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny

#### By GARDINER HARRIS and ROBERT PEAR

WASHINGTON — For years, Novo Nordisk, a Danish company and one of the earliest makers of insulin, has raced behind Eli Lilly to capture the lucrative insulin market in the United States.

When in 1996 Lilly started selling Humalog, a synthetic insulin with speedier blood-sugar control, Novo needed four more years to get approval to market a similar product.

When Lilly's huge sales force put Novo at a disadvantage, Novo fought back. The company hired hundreds of sales representatives. When Lilly struck a marketing deal with the Eckerd pharmacy chain, Novo responded with a partnership with Rite Aid.

But in its race, several former Novo sales representatives say, Novo may have crossed the line. Sales representatives paid at least one Rite Aid pharmacist to encourage switches from Lilly products or Novo's own lower-priced versions to higher-priced ones, according to documents and former and present company officials. Novo also paid doctors' assistants when prescriptions were switched, according to two former sales representatives.

Several former sales representatives said they were told by pharmacists and doctors' assistants that some patients first became aware of the switches when they picked up the new medicines at a pharmacy.

Officials from Novo and Rite Aid said that their activities were intended primarily to educate patients or improve care and that similar programs were common in the industry.

Karen A. Rugen, a spokeswoman for Rite Aid, said, "Our alliance with Novo Nordisk is standard industry practice." Ms. Rugen said, however, that Novo had paid one of Rite Aid's pharmacists directly, although she said that top Rite Aid executives had been unaware of the practice.

Susan Jackson, a spokeswoman for Novo Nordisk, said that the overall agreement between Novo Nordisk and Rite Aid "has benefited many people with diabetes."

Ms. Jackson would not address questions about payments made to doctors' assistants or a Rite Aid pharmacist, nor would she say how much Novo paid Rite Aid. But she said the partnership "is not unlike other agreements common in the industry that provide 'preferred status' for branded drugs."

But prosecutors are now investigating possible criminal violations. On Dec. 20, Novo said it had received a subpoena from the United States attorney for the Eastern District of New York for documents relating to its marketing practices.

The company said that it "believes that the investigation is limited to its insulin products." The subpoena indicated that "the documents are necessary for the investigation of potential criminal offenses," the company said.

Drug companies may pay for consulting or educational services, but federal anti-kickback statutes prohibit them from offering financial incentives to doctors or pharmacists to encourage or reward the prescribing of particular drugs, according to a 2003 guidance from the Department of Health and Human Services.

"In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful" in health care, the guidance states.

#### A Marketing Battle

The rivalry between Novo and Lilly illustrates the efforts companies will undertake to become No. 1 in a drug market, especially for chronic diseases like diabetes, which in the United States is a \$3.3 billion market annually, according to IMS Health, a pharmaceutical information and consulting company.

From a business perspective, Novo's efforts were a great success. From December 2001 through November 2005, Novo's insulin sales rose 364 percent to \$963 million while Lilly's insulin sales rose only 13 percent to \$1.43 billion, according to figures provided by IMS Health.

The marketing programs were detailed in dozens of internal Novo and Rite Aid documents obtained by The New York Times. Three former Novo sales representatives described the programs. These people, some of whom spoke to The Times separately from one another, do not wish their names to be used because all still work in the industry and fear retribution. Parts of the programs were also confirmed by company officials and another sales representative who allowed their names to be used. The former sales representatives would not comment on whether they had filed whistle-blower lawsuits against Novo.

In its marketing battle with Lilly, Novo's sales representatives undertook a variety of efforts to persuade doctors to prescribe Novo's insulin products, one of which was known as the "anchor in the office" program.

Under this program, Novo sales representatives established contacts in some medical offices that served many diabetics, three former sales representatives said. The contacts were generally

nurses or medical assistants responsible for monitoring diabetic patients. Officially, Novo paid these "anchors" to educate patients about Novo's products.

But two of the three former sales representatives who participated in the program said that Novo paid anchors as much as \$25 for each prescription they helped switch to higher-priced insulin products.

Vikki Tolbert, a Novo district sales manager, said in an interview that "people are up in arms for no reason."

"Novo, like other companies, used to have a program to reimburse nurses and medical assistants," Ms. Tolbert said. "The purpose was not to switch patients, but to educate them and train them on insulin and insulin devices."

The formal program and the payments ended several years ago, Ms. Tolbert said, but some sales representatives still wanted to have trainers, or "anchors in the office."

"We would never tell a sales rep to pay anyone," Ms. Tolbert said. "That's crazy. But some reps do things of their own volition. They are out in the field by themselves every day. Managers are not with them. A pharmaceutical company cannot know what each individual sales rep is doing."

#### Deals Becoming Routine

A number of drug companies are running afoul of the anti-kickback law. In October, Serono Laboratories pleaded guilty to two counts of conspiracy and agreed to pay \$704 million to settle criminal charges that it engaged in an elaborate kickback scheme to encourage sales of its <u>AIDS</u> drug, Serostim. In 2004, prosecutors accused Pfizer of paying doctors to prescribe its <u>epilepsy</u> drug Neurontin, and the company pleaded guilty to two criminal charges and paid \$430 million.

State and federal prosecutors are investigating scores of other criminal and civil cases of marketing abuse, all of which are under seal. The possible health consequences for patients are rarely emphasized, however. For instance, physicians say aggressive marketing of insulin products can hurt patients.

Dr. David M. Nathan, director of the diabetes center at Massachusetts General Hospital and professor at Harvard Medical School, said that switching insulin prescriptions without providing thorough counseling to patients can be dangerous.

Newer, more expensive rapid-acting insulins begin working within five minutes. Older, cheaper insulins take 30 to 40 minutes to lower blood-sugar levels. Patients who are switched from older to newer insulins without their knowledge may wait too long to eat, Dr. Nathan said.

"If their blood-sugar levels drop too low, they can become confused, lose coordination, lose consciousness and have seizures," Dr. Nathan said. "This can result in accidents and even death."

Drug makers routinely provide financial incentives to managed-care firms for greater sales, but providing similar incentives to pharmacy chains can raise legal and ethical questions in part because pharmacists' advice to patients, like that of doctors', is supposed to be based on the best interests of patients, not pharmacists.

Still, deals between drug makers and pharmacy chains are now routine. As part of these deals, drug companies pay pharmacy chains for drug promotions that can range from simple refill reminders to efforts to switch patients to higher-priced drugs. If sales then rise, payments can increase, said Jeffrey Krinsk, a lawyer in San Diego who specializes in suing over the deals.

The companies say that these arrangements benefit patients, but some pharmacy regulators disagree, saying the partnerships may result in prescriptions being switched inappropriately, hurting patients.

David R. Work, executive director of the North Carolina Board of Pharmacy, said that his board had tried unsuccessfully to restrict such deals, one of the few boards to make such an effort. The practice of pharmacy, like that of medicine, is regulated by state boards.

"These switches have nothing to do with patient interest, they're all about money," Mr. Work said.

Novo's marketing campaigns also highlight the conflicting loyalties of many health care professionals. Doctors and their staff often consult for or receive gifts from drug makers, which may affect prescribing decisions. Pharmacists sometimes suggest one drug over another to patients for financial, not medical, reasons, pharmacy regulators say.

In April 2004, Novo Nordisk sent information to its field managers and sales representatives about marketing guidelines issued by the federal government and by a trade association for the pharmaceutical industry.

After reviewing the guidelines, a Novo sales representative sent an e-mail message to Ms. Tolbert, the Novo district manager, asking, "Are we allowed to do the anchors in the office then?" Ms. Tolbert replied, "As far as I know, and in discussing it with other managers, we are allowed to compensate for patient education."

In March 2004, Ms. Tolbert sent an e-mail message to sales representatives describing the purpose of Novo's marketing efforts.

"Our goal is 50 or more scripts per week for each territory," Ms. Tolbert wrote, according to a copy of the message provided to The Times. "If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!!""

Preceptorships are consulting arrangements with doctors.

After Novo announced its partnership with Rite Aid in March 2002, Ms. Jackson, the Novo spokeswoman, was quoted in Diabetes Health magazine explaining that Rite Aid pharmacists "will actively intervene to introduce Novo Nordisk products."

Novo Nordisk produces a variety of insulin products, including preloaded syringes and synthetic versions. These products are often more convenient to use but are also more expensive than standard insulin. Since diabetes is a difficult disease to manage, convenience is important. But some doctors question whether the convenience of the new products is worth the premium prices.

#### One Pharmacist's Role

Lawrence M. Schultz, a Rite Aid pharmacist in Maryland, was paid by Novo to identify diabetics from databases in Rite Aid pharmacies, according to the three former Novo sales representatives.

Mr. Schultz or a pharmacy technician then contacted doctors to persuade them to switch their patients to higher-priced insulin products, according to the three former sales representatives. It is not known why doctors agreed to the changes, but the sales representatives say that they may have assumed the switch was required under the patient's insurance policy.

Two former sales representatives who contracted with Mr. Schultz and hired "anchors" say that Mr. Schultz, doctors' assistants and others told them that patients often only became aware that their prescriptions had been switched to a different insulin when they arrived at the pharmacy to pick up their medicines. The sales representatives said they knew of no patients who were directly harmed by these surprise switches.

Ms. Rugen of Rite Aid acknowledged that Rite Aid has a partnership with Novo but says that "no official at Rite Aid knew that Larry Schultz," the Rite Aid pharmacist, "was being paid by Novo Nordisk."

Mr. Schultz confirmed that he had "pushed Novo Nordisk" products. He refused to give details, but said: "Everything I did was done completely ethically. The one thing I would never do is put my job, or Rite Aid, in jeopardy."

Three Novo sales representatives who described Mr. Schultz's efforts on their behalf said they knew of no other Rite Aid pharmacist who received payments directly from Novo. But internal documents from Rite Aid provided to The Times show that Rite Aid executives urged pharmacists throughout the chain to dispense Novo products.

Rite Aid encouraged pharmacists to run computerized "drug utilization reports" to identify patients who could be switched, documents show.

Rite Aid had powerful financial incentives, documents show. In a letter to Rite Aid pharmacists in February 2005, top Rite Aid executives said, "Each Novo Nordisk product we dispense brings us 20 to 40 percent better profit margin." Moreover, they said, such sales add millions of dollars to Rite Aid's "bottom line."

Ms. Jackson, the Novo spokeswoman, said the company was "pursuing this matter with great urgency" and intended "to take remedial action in the event we find violations of our policies."

Carmen Catizone, executive director of the National Association of Boards of Pharmacy, said marketing deals between drug companies and pharmacy chains had often misled doctors and hurt patients.

"We are opposed to plans where the financial interest of the manufacturer takes precedence over the patient's health," Mr. Catizone said. "To call a physician and say that we're changing a patient's medication and make it seem as if it's on behalf of the patient when it's actually part of this marketing deal is not right."

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## Statement



### In Opposition to Kansas Senate Bill 229 February 15, 2007

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes any restriction on the use of prescribing data. Kansas Senate Bill 229 restricts pharmaceutical manufacturer use of prescriber data. This restriction could have an adverse impact on patients as it could result in a physician's inability to have the latest information on a prescription drug and could potentially impact patient safety. Pharmaceutical manufacturers regularly partner with physicians and the Food and Drug Administration to ensure patient safety and provide education.

Banning the use of prescribing data could result in significant unintended consequences that could adversely impact patient care and safety and hamper manufacturers' ability to alert physicians of important new drug information. This data is critical to the efficient, timely, and targeted dissemination of information to doctors and patients. PhRMA recognizes physicians' concerns with the inappropriate use of prescriber data and supports the American Medical Association's (AMA) Prescription Data Restriction Program (PDRP). PhRMA and the AMA believe that this program strikes the appropriate balance between the concerns of physicians by providing an opt-out mechanism and ensuring access to prescriber data that is critical for health research and patient safety.

#### Patient Identifiable Information Is Protected

 The Health Insurance Portability and Accountability Act of 1996 (HIPAA) bars any use of patient identifiable information. Therefore, under federal law, the use of prescriber data cannot include individual patient identifiable information.

#### **Prescriber Data Is Critical for Patient Safety**

Below, are methods that pharmaceutical companies use to transfer timely information to physicians and ultimately to patients to ensure optimal patient safety:

- Drug recall: The Food and Drug Administration (FDA) regulations require, for some types of
  problems with medicines, that the pharmaceutical company notify physicians that the company
  is recalling the drug. Without access to prescriber-specific data, it becomes extremely difficult
  for pharmaceutical companies to conduct targeted and effective recalls in accord with FDA
  standards, such as providing status reports on the recall, as quickly as possible.
- "Dear Healthcare Provider" letter: These letters are typically used to alert physicians about new information regarding the risks associated with a particular drug. The letters also function to provide physicians with important information regarding drug shortages.
- Adverse health reporting: Federal law requires pharmaceutical companies to report to FDA any adverse event associated with an approved drug. Prescriber-specific data can be a useful tool when a company needs to find all the necessary data about such an event.
- Labeling changes: Physicians should maintain current knowledge of FDA-approved labeling
  for the drugs they prescribe. Targeted communications are one of the ways in which companies
  notify physicians of the most important new safety information, including black box warnings,
  drug-drug interactions, and emerging adverse events.

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Senate Public Health and Welfare Committee Attachment # 12 February 15, 2007 • 'Risk management plan': FDA may require the manufacturer of a medicine to implement a 'risk management plan' to address a particularly troubling safety issue. These plans may require the pharmaceutical company to monitor prescribing practices and to ensure that individual physicians are communicating critical safety information to patients. FDA required risk management and risk minimization plans rely on the use of prescriber data. Any restrictions placed on this use could impair access to higher-risk drugs used to treat diseases such as cancer, leukemia, diabetes, epilepsy, and multiple sclerosis.

#### **Educating Physicians**

- Access to prescriber data allows pharmaceutical companies to target necessary prescription information to physicians which helps to avoid a saturation of less relevant information to a broader physician audience. Legislation that bans certain uses of prescriber data could jeopardize a physician's ability to provide quality care by restricting access to critical information about medicines.
- Manufacturers' use of prescriber data can help reinforce appropriate prescription drug compliance which may help reduce costs through proper patient and dose selection. It also can help implement education programs by medical professionals which assist in proper utilization which also may reduce overall costs.

#### Elements of the PDRP Program

- The AMA's PDRP provides physicians with an opt-out mechanism to prohibit the release of their
  prescribing data to pharmaceutical sales representatives for a period of three years as well as
  an avenue for registering complaints against companies or individuals who have used
  prescriber data inappropriately.
- Physicians can easily opt-out by logging on to <u>www.ama-assn.org/go/prescribingdata</u> or by requesting the restriction via phone, fax, email, or standard mail and pharmaceutical companies must ensure compliance with the PDRP by processing restriction requests within 90 days.
- As part of the program, the AMA also provides physicians with information on what the AMA considers responsible use of prescribing data by pharmaceutical companies.

#### Physician Reaction to the PDRP

 An AMA-commissioned Gallup Poll found in 2004 that two-thirds of doctors surveyed were opposed to the release of prescribing data to pharmaceutical representatives, but 77% of those physicians felt that the AMA "opt-out" program would alleviate concerns about the release of data.<sup>1</sup>

For the reasons set forth above and in an effort to protect the safety of patients, PhRMA urges Kansas legislators to oppose any ban on the use of physician prescribing data.

<sup>&</sup>lt;sup>1</sup> Staphanie Saul, NYT,"Docs Object to Gathering of Drug Data." May 4, 2006.