

Approved 2-7-85
Date sh

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by Representative Marvin L. Littlejohn at
Chairperson

1:30 a.m./p.m. on February 6, 1985 in room 423-S of the Capitol.

All members were present except:

Committee staff present:

Emalene Correll, Research
Norman Furse, Revisor
Sue Hill, Secy. to Committee

Conferees appearing before the committee:

Mr. Ken Schafermeyer, Exec. Secy of Ks. Pharmacists Association
Mr. Everett Willoughby, Exec. Secy. of Kansas Board of Pharmacy
Mr. Bill Dean, Mgr. of Government Affairs for Merrel Dow Pharmaceuticals, Inc.
Mr. Harold Riehm, Exec. Director of Ks. Assn. of Osteopathic Medicine
Jerry Slaughter, Ks. Medical Society
Dr. Robert Harder, Secy. Dept. of Ks. Social Rehabilitation Services, (SRS)
Lois Scibetta, R.N. Ph.D., Exec. Administrator of Ks. State Board of Nursing
Lynelle King, Exec. Director of Ks. State Nurses' Association

Visitor's register, (Attachment No. 1.)

Chairman called meeting to order by continuing hearings on HB 2077.

HB 2077

Mr. Ken Schafermeyer answered questions from committee, i.e., yes, I do feel the raising costs of prescription medication is partly due to product liability; and yes, our Association does feel that cost savings for generic drugs could be achieved by the legislation we have now in the Senate committee, i.e., (MAC). It is reasonable legislation, and would save many dollars for the state. We are not asking for anything that is outside the realm of reason.

Mr. Everett Willoughby gave testimony to HB 2077, (see Attachment No. 2), for details. He spoke to concerns that the monitoring done by their Board could possibly increase with the passing of this bill, and the fiscal impact would necessitate their hiring another inspector, and total costs could reach \$40,000 annually. He then answered questions from committee.

Mr. Bill Dean, Merrell Dow, presented printed testimony to committee, (see Attachment No. 3), for details. He asked to clarify a comment made in hearings yesterday in regard to patents on drugs, he checked, and the maximum length of patent on a new drug is 10 years. The cost today to bring a new drug to the market, from beginning to the market place, is \$86 Million. He continued urging committee to review two major considerations, i.e., potential economic benefit to SRS, (and Ks. taxpayers), and the effect on patients health care. He feels, pharmacists and physicians share the view that drug product selection, even if it involves a generically equivalent product made by a reputable firm is inappropriate for many patients. To conclude he said drug therapy, in order to be medically sound and cost effective depends on clinical and medical judgments which can best be made by health practitioners and patients; these decisions should not be dictated by rigid provisions of a statute; and legislation or regulation should be shaped to accomodate individual needs of patients and the best judgment of health professionals. He urged committee to not approve HB 2077.

Mr. Harold Riehm, Exec. Director of Ks. Assn. of Osteopathic Medicine had presented printed testimony to committee, (see Attachment No. 4.), for details. He spoke in opposition fo HB 2077, saying there are osteopathic physicians who regularly permit brand exchange, and there are others that for various reasons prefer brand drugs to be given to their patients. He urged for a system which permits the physician, by simple placement of signature to permit brand exchange, but still maintain physician discretion when they so choose. He answered questions from committee.

Unless specifically noted, the individual remarks recorded herein have not been transcribed verbatim. Individual remarks as reported herein have not been submitted to the individuals appearing before the committee for editing or corrections.

CONTINUATION SHEET

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE,
room 423-S, Statehouse, at 1:30 a.m./p.m. on February 6, 1985

Chair had committee note that Dr. Harder had prepared an amendment on HB 2077, and he asked Mr. Slaughter if he wished to make his comments before the amendment is presented today, or wait until after it has been read. Mr. Slaughter chose to make brief comments.

Mr. Jerry Slaughter, of Ks. Medical Society then spoke to committee on HB 2077, stating he would not present his printed testimony since the amendment is to be discussed, and his testimony had been written before he was aware of the proposed changes. He did comment, however, that he does oppose the bill the way it is now written. He appreciates the position of Dr. Harder and SRS, as they have a difficult time funding a program that isn't particularly popular, and difficult problems trying to cut costs, etc. He stated the Ks. Medical Society is well aware of the good intentions of Dr. Harder and the SRS as they try to limit costs.

Chair recognized Dr. Robert Harder, SRS, who presented an amendment for HB 2077, (see Attachment No. 5.), for details. These changes are indicated on Page 2 of the attachment. The proposed amendment would broaden the language so that the pharmacists will not be in violation if; the generic equivalent of the prescribed drug is unavailable, that the prescriber requests the exchange in his own handwriting, or the generic drug is not bioequivalent.

There were many questions after Dr. Harder's amendment was read, and Chair then appointed a sub-committee of Rep. Foster as Chairman, Rep. Harder, and Rep. Neufeld to study this proposed amendment, and report their recommendations to committee the early part of next week.

Chair stated there would then be no further work done on HB 2077 today.

HB 2082:

Chair recognized Dr. Lois Scibetta, of Ks. Board of Nursing, and she spoke to HB 2082. She presented printed testimony to committee, and there were charts that indicated costs to their Board of \$21.50 per candidate; Registered Nurses, and Licensed Practical Nurses. She explained nurses can be, (and many are), licensed in several states, and this is part of the reasoning for the request for HB 2082. There are two components for this bill; one direct payment for the examination booklet and scoring by the candidate to the examination service. The second, deals with their interstate disciplinary matters. She then spoke to an amendment they wish to have added to the bill, i.e., fee limitations that are shown in detail on page one of her testimony. (See Attachment No. 6.), for details of Dr. Scibetta's testimony.

Lynelle King, Ks. State Nurses Association began her testimony to HB 2082, giving some background of her Association for the benefit of new committee members. She then spoke of the St. Nurses Association's support to the Bd. of Nursing in being able to better regulate nurses who hold licenses in Kansas and other states as well, and HB 2082, if passed, would make provision for the St. Board to hold hearings related to continuing licensure, revoke/suspension/or limitation of said licensure when deemed necessary. The St. Nurses Association had no opinion in regard to the request for fee increases she said, and they reluctantly agree with the collection of examination fees. She then answered questions from committee. (See Attachment No. 7.), for details.

Hearings closed on HB 2082.

Meeting adjourned at 2:58 p.m.

Kansas State Board of Pharmacy

*Attn. # 1
2-6-85*

503 KANSAS AVENUE, SUITE 328
P.O. BOX 1007
TOPEKA, KANSAS 66601
PHONE (913) 296-4056

STATE OF KANSAS



JOHN CARLIN
GOVERNOR

EVERETT L. WILLOUGHBY
EXECUTIVE SECRETARY

ROBERT E. DAVIS
BOARD ATTORNEY

TO: Members of the House Committee on
Public Health and Welfare

FROM: Everett L. Willoughby
Executive Secretary
Kansas State Board of Pharmacy

DATE: February 5, 1985

RE: House Bill 2077

I have reviewed House Bill 2077, which, if enacted, would require a pharmacist to dispense a bioequivalent generic drug to a consumer receiving medical assistance from the Department of Social and Rehabilitation Services. The only exception would be that a brand name drug could be dispensed providing the prescribing practitioner completed and signed a special form documenting that the brand name drug prescribed is medically necessary for the treatment of the person for which the drug is being prescribed. This special form would then have to be attached to the prescription and retained by the pharmacy for a period of five years.

HB 2077 would amend K.S.A. 65-1637, which is administered by the Board of Pharmacy. Therefore, its monitoring would be the responsibility of the three Inspectors now retained by the Board. It possibly would add time involved to each inspection, thereby limiting the number of daily inspections accomplished by each Inspector. The number of violations encountered could conceivably result in additional hearings before the Board of Pharmacy for the pharmacist and pharmacy involved in the violations.

If few violations are uncovered, the monitoring could be done by our present staff and the fiscal impact minimal. If many violations are reported and investigations with hearings to follow, the fiscal impact could necessitate the hiring of an

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Members of the House Committee on
Public Health and Welfare
February 5, 1985
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Inspector at the present salary of \$21,912 yearly, plus leasing an automobile at the rate of 22¢ per mile and per diem payments of \$10.00 per quarter, plus the possibility of one additional Board meeting each year.

The long range fiscal impact could conceivably amount to approximately \$30,000 annually. The Board of Pharmacy is a fee agency, and the additional amount budgeted would probably necessitate the increasing of fees to all pharmacists and pharmacies.

ELW:arb

Merrell



MERRELL DOW PHARMACEUTICALS INC.
Subsidiary of The Dow Chemical Company
Cincinnati, Ohio 45216

WILLIAM A. DEAN Government Affairs Area Manager
8304 Connell
Overland Park, KS 66212
(913) 648-3205 or
800-543-3000, EXT 4556

FEBRUARY 6, 1985

STATEMENT TO HOUSE PUBLIC HEALTH & WELFARE COMMITTEE

Subject: House Bill 2077, Mandatory Generics - Medicaid

Mr. Chairman and members of the committee:

My name is Bill Dean and I am Government Affairs Manager for Merrell Dow Pharmaceuticals Inc. residing in Overland Park.

I am opposed to the mandatory use of generic drugs for Medicaid patients as proposed in HB 2077.

First, I'd like to update Sue Ellen Webber's information. Under the new ANDA-Patent Extension Bill passed by Congress late in 1984, the maximum length of a patent on a new drug is 10 years.

It was also brought out that drug costs had increased 37% in the 1980-1984 period. Interestingly the cost of bringing a new drug to market in 1980 was approximately \$55 to \$60 million and in 1984, the cost had increased to over \$80 millions due to the federal government's increased requirements for more clinical information. The "paper work" for a new drug application (NDA) used to be 13 feet high when stacked page atop page. Now, it fills a boxcar!

COMING BACK TO THE TOPIC OF TODAY, MANDATORY DPS FOR MEDICAID PATIENTS. I URGE THE COMMITTEE TO REVIEW TWO MAJOR CONSIDERATIONS:

1. The potential economic benefit to SRS (& KS TAXPAYERS)
2. The effect on patients health care.

SAVINGS:

There is potential for significant savings from generic drug product selection laws. 25% of all drugs are available from multi-source manufacturers. The reason for the large gap between potential savings and actual savings can be found in basic economic and professional practice realities.

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Physicians and Pharmacists continue to primarily prescribe and dispense the drug products of established reputable manufacturers. They do not usually use the lowest-cost generic product on the market, which would result in more savings, either because it is not always available or because they do not have confidence in its manufacturers and the possibility of litigation is ever present. It may not be economically feasible for pharmacists to stock duplicate generic inventory for every multi-source drug.

Finally, pharmacists and physicians share the universally-held medical view that drug product selection, even if it involves a generically equivalent product made by a reputable firm, is inappropriate for many patients.

In pursuing the objective of mandating the use of generic drugs to effect savings to the Kansas Medicaid Drug Program, the legislature should not do so to the exclusion of essential patient health care considerations.

Drug therapy plays a preventive and cost-effective role in health care delivery. Decisions about the most appropriate drug therapy should involve all parties involved... physician, pharmacist and the patient.

These decisions should be based on both economic and medical considerations, taking into account the unique needs of individual patients and the characteristics of a particular drug.

Mr. Schafermeyer discussed the FTC's advocating state drug product selection laws an important point is the fact the FTC (1979) recommended in its report that such laws be permissive in nature.

CONCLUSION:

1. Drug therapy that is both medically sound and cost effective depends on clinical and medical judgments which can best be made by health practitioners and patients.
2. Decisions about drug selection must be based on both medical and economic considerations, and take into account the unique characteristics of specific drugs and the needs of individuals. These decisions should not be dictated by the rigid provisions of a statute.
3. To the extent that drug therapy and drug selection is the subject of public policy legislation or regulation should be shaped to accommodate the individual needs of patients and the best professional judgment of health professionals.

I'm concerned with the mandating of medical therapy and the liability which goes hand in hand with it. I urge you not to approve HB 2077.

#4



Kansas Association of Osteopathic Medicine

TESTIMONY OF THE KANSAS ASSOCIATION OF OSTEOPATHIC MEDICINE ON H.B. 2077

Chairman Littlejohn and Members of the Committee:

My name is Harold Riehm and I am Executive Director of The Kansas Assn. of Osteopathic Medicine. For the 175 member physicians I represent, we express our opposition to H.B. 2077.

Osteopathic physicians are proud of the extent of services provided to those who are participants in the Medicaid and Medikan programs. Increasingly, however, new regulations are widening the gap between care available to such participants and those not on such programs.

We view this proposal--to require pharmacist brand exchange--as one additional step of this developing two-tiers of medical care.

Though there are osteopathic physicians who regularly permit brand exchange on their prescription forms, there are others that, for a variety of reasons, prefer certain prescriptions to be filled with the brands they indicate. In some instances it is because the physician and patient have long used that specific brand, and feel comfortable with it. In others, it may be that the physician has some reason to question the quality control used in the manufacture of the generic version. Or, it may be simply that the physician views prescribing as a critical part of the health care process and prefers not to entrust brand selection to a third party, for certain drugs.

Though H.B. 2077 does permit the provider to indicate that a specific brand name is medically necessary, it is unclear what form that would take, or how much physician time or "documentation" would be required.

Because of these feelings among our physician members, KAOM urges you to maintain the present system which permits the physician, by simple placement of signature, to permit brand exchange, but still maintains physician discretion when he or she chooses.

I close by stating that the minutes of this Committee's hearing on a similar bill last session, indicate that the Secretary of SRS planned to meet with prescribing providers and the pharmacy association to discuss differences regarding this proposal. I note that if such a meeting were held between sessions, the Kansas Association of Osteopathic Medicine was not so informed.

1325 TOPEKA BOULEVARD
TOPEKA, KANSAS 66612, (913) 234-5563

HAROLD E. RIEHM, EXECUTIVE DIRECTOR

*Attn. #4
2-6-85*

HOUSE BILL No. 2077

By Committee on Public Health and Welfare

1-25

0017 AN ACT concerning prescriptions for drugs; amending K.S.A.
0018 65-1637 and repealing the existing section.

0019 *Be it enacted by the Legislature of the State of Kansas:*

0020 Section 1. K.S.A. 65-1637 is hereby amended to read as fol-
0021 lows: 65-1637. In every store, shop or other place defined in this
0022 act as a "pharmacy" there shall be a registered pharmacist in
0023 charge and the compounding and putting up of prescriptions
0024 shall be limited to registered pharmacists only. Except as other-
0025 wise provided by the pharmacy act of this state, when a pharma-
0026 cist is not in attendance at a pharmacy, the premises shall be
0027 enclosed and secured. Prescription orders may be written, oral or
0028 telephonic. Blank forms for written prescription orders may have
0029 two signature lines. The first signature line shall state: "Dis-
0030 pense as written _____." The second signature line
0031 shall state: "Brand exchange permissible _____."
0032 Prescriptions shall only be filled or refilled in accordance with
0033 the following requirements:

0034 (a) ~~All~~ Subject to the provisions of subsection (b), all pre-
0035 scriptions shall be filled in strict conformity with any directions
0036 of the prescriber, except that a pharmacist who receives a pre-
0037 scription order for a brand name drug product may exercise
0038 brand exchange with a view toward achieving a lesser cost to the
0039 purchaser unless:

0040 (1) The prescriber, in the case of a prescription signed by the
0041 prescriber and written on a blank form containing two signature
0042 lines, signs the first signature line following the statement "dis-
0043 pense as written _____," or

0044 (2) the prescriber, in the case of a prescription signed by the
0045 prescriber, writes in ~~his or her~~ the prescriber's own handwriting

#5

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2-6-1985

0046 "dispense as written" on the prescription, or

0047 (3) the prescriber, in the case of a prescription other than one
0048 in writing signed by the prescriber, expressly indicates the
0049 prescription is to be dispensed as communicated, or

0050 (4) the federal food and drug administration has determined
0051 that a drug product of the same generic name is not bioequiva-
0052 lent to the prescribed brand name prescription medication.

0053 (b) A pharmacist who receives a prescription order for a
0054 brand name drug product shall exercise brand exchange with a
0055 view toward achieving a lesser cost to the purchaser if the
0056 prescribed drug is being dispensed under a plan developed by
0057 the secretary of social and rehabilitation services pursuant to
0058 subsection (s) of K.S.A. 39-708c and amendments thereto, unless
0059 the federal food and drug administration has determined that a

0060 drug product of the same generic name is not bioequivalent to
0061 the prescribed brand name ~~prescription~~ medication or the pre-
0062 scriber transmits ~~with the prescription order a form provided~~
0063 ~~by the secretary of social and rehabilitation services, completed~~
0064 ~~and signed by the prescriber which documents that the specific~~
0065 ~~brand name drug product prescribed is medically necessary for~~
0066 ~~the treatment of the person for whom the drug is being pre-~~
0067 ~~scribed. A pharmacist shall maintain any form filed pursuant to~~
0068 ~~this subsection with the prescription order record for a period of~~
0069 ~~five years.~~

0070 (b) (c) Prescription orders shall be recorded in writing by the
0071 pharmacist and the record so made by the pharmacist shall
0072 constitute the original prescription to be dispensed by the phar-
0073 macist. This record, if telephoned by other than the physician
0074 shall bear the name of the person so telephoning. Nothing in this
0075 paragraph shall be construed as altering or affecting in any way
0076 laws of this state or any federal act requiring a written prescrip-
0077 tion order.

0078 (e) (d) No prescription shall be refilled, if it contains a state-
0079 ment that it is not to be refilled.

0080 (d) (e) If any prescription order contains a provision that the
0081 prescription may be refilled a specific number of times within or
0082 during any particular period, such prescription shall not be

(1)
(2)
in the prescriber's own handwriting on the prescription order form the statement "brand name medically necessary," or (3) the pharmacist dispensing the prescription does not have available in the pharmacy inventory a bio-equivalent generic drug for the brand name medication prescribed.

0083 refilled except in strict conformity with such requirements.

0084 (⇔) (f) If a prescription order contains a statement that during
0085 any particular time the prescription may be refilled at will, there
0086 shall be no limitation as to the number of times that such
0087 prescription may be refilled except that it may not be refilled
0088 after the expiration of the time specified.

0089 (⇔) (g) Any pharmacist who exercises brand exchange and
0090 dispenses a less expensive drug product shall not charge the
0091 purchaser more than the regular and customary retail price for
0092 the dispensed drug.

0093 Nothing contained in this section shall be construed as pre-
0094 venting a pharmacist from refusing to fill or refill any prescrip-
0095 tion if in ~~his or her~~ *the pharmacist's* professional judgment and
0096 discretion such pharmacist is of the opinion that it should not be
0097 filled or refilled.

0098 Sec. 2. K.S.A. 65-1637 is hereby repealed.

0099 Sec. 3. This act shall take effect and be in force from and
0100 after its publication in the statute book.

Attn. #6
2-6-5



KANSAS STATE BOARD OF NURSING

BOX 1098, 503 KANSAS AVENUE, SUITE 330
TOPEKA, KANSAS 66601

Telephone 913/296-4929

TO: The Honorable Marvin Littlejohn, Chairman, and Members of the
Public Health and Welfare Committee

FROM: Dr. Lois Rich Scibetta, Executive Administrator

RE: House Bill 2082 - Suggested Amendments

DATE: February 6, 1985

Thank you Mr. Chairman for the opportunity to speak in support of House Bill 2082. The Board of Nursing thanks the Committee for introducing this Bill.

House Bill 2082 has two components, one, direct payment for the examination booklet and scoring by the candidate to the examination service. The second aspect of the Bill deals with our interstate disciplinary matters.

As mentioned last time when I appeared before this Committee, the direct application of payment will cut the fee expenditures for the Board of Nursing. I have diagrammed the manner in which individual fees are apportioned. You will note that the Board of Nursing, particularly with the LPN fee, does not retain very much of the fee. It should also be noted that there is a single fee for licensure and examination. Most, or many, boards have one fee for examination and one fee for licensure.

Today, I am proposing an amended section of the original Bill. The amended section consists of lines 0027 - 0036, and will enable the Board to raise the statutory maximums for fees. The Board of Nursing has been at the maximum for some time, and although we do not anticipate a fee increase immediately, it will be necessary in the future.

0024 Section 1. K.S.A. 65-1118 is hereby amended to read as fol-
 0025 ows: 65-1118. (a) The board shall collect in advance fees pro-
 0026 vided for in this act as fixed by the board, but not exceeding:

0027 Application for license-professional nurse.....	\$60	\$75
0029 Application for license-practical nurse.....	\$35	\$50
0031 Application for biennial renewal of license-		
0032 professional nurse and practical nurse.....	\$25	\$40
0034 Application for reinstatement of license.....	\$35	\$50
0036 Certified copy of license.....	\$ 6	\$25

This has been discussed with our budget analyst who is in agreement. I would like to call your attention to two items in the fee structure, line 0034, reinstatement of a license and line 0035, certified copy of a license.

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The Honorable Marvin Littlejohn

February 6, 1985

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In the past, both of these office/Board functions take a great deal of clerical and some professional time and they have been underpriced as a service to our licensees.

I would request the Committee to report House Bill 2082 out favorably for passage.

Thank you. I will be happy to answer any questions which you may have.

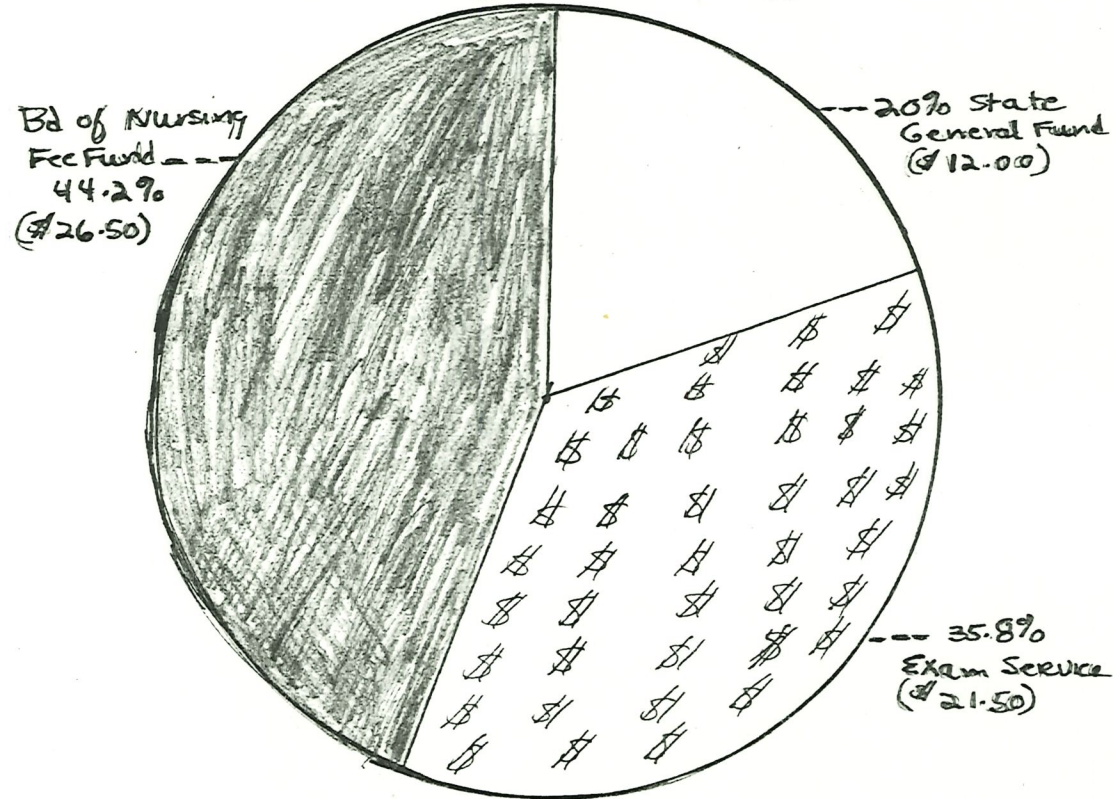
Kansas State Board of NURSING

Licensure By Examination - Fees

Registered Nurse:

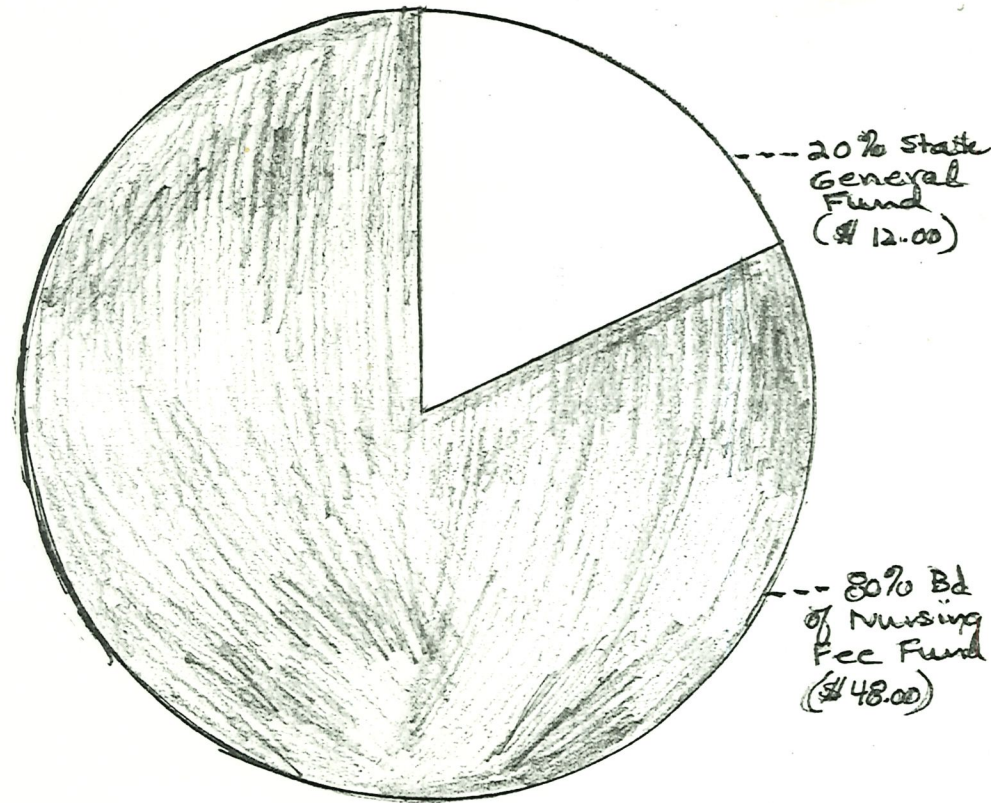
Prior to 7/84

\$60⁰⁰ Fee = 100%



Current

\$60⁰⁰ Fee = 100%



Explanation:

- 1) one fee for licensure and examination
- 2) Fee fund retained 26.50 of 60.00 fee for RN's for examination and licensure
- 3) Exam fee is only for use of exam booklet and scoring. Board class all candidates.
- 4) Cost for use of examination is \$21.50 if Board pays, and \$18.50 if candidate pays direct.
- 5) 50 nursing Boards use direct payment procedure.

Legend

- state General Fund
- Bd of Nursing Fee Fund
- Examination Service pd. by Board

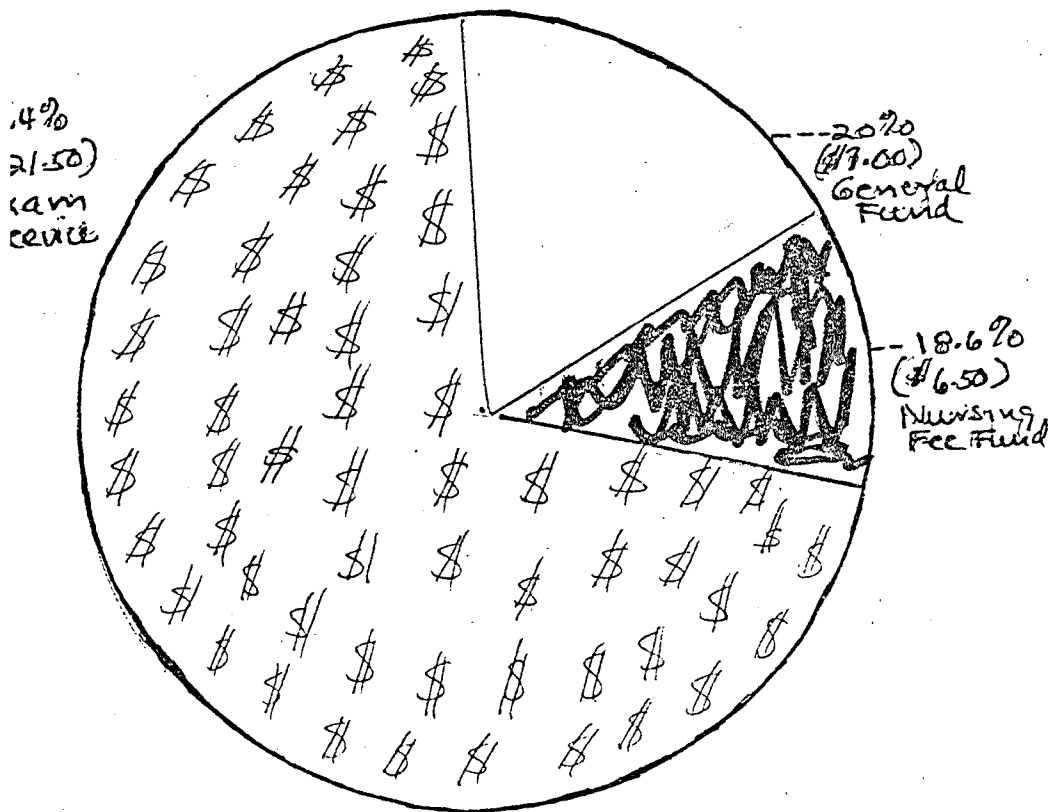
Kansas State Board of Nursing

Licensure By Examination - Fees

Licensed Practical Nurses:

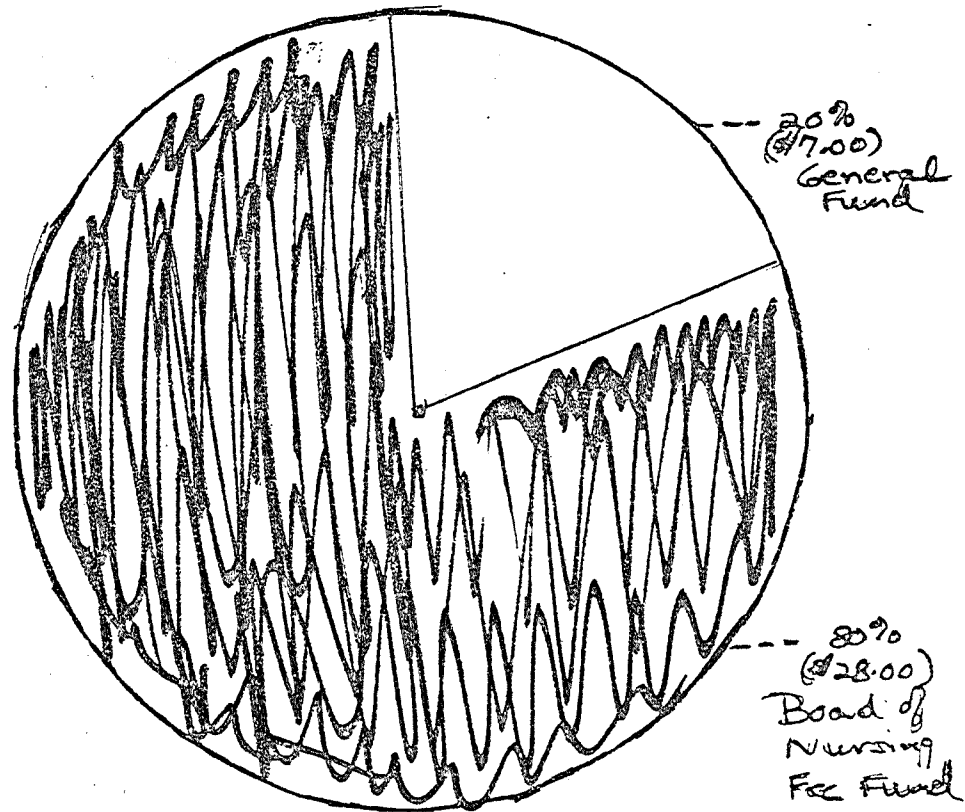
Prior to 7/84

\$35.00 Fee = 100%



Current

\$35.00 Fee = 100%



Explanation:

- 1) Prior to 7/84, the Board paid out 81.4% of fee, or \$28.50 of 35.00 fee for the General fund, and to exam service.
- 2) Less dollars retained with LPN's cost of exam the same to the Board (\$21.50)
- 3) By having the candidate pay for exam booklet, Bd of Nursing Fee fund retains 80% of licensure fee, and expenditures (to exam service) out
- 4) One fee for both licensure and examination

Legend

- ----- St. General Fund
- ▨ ----- Bd. of Nursing Fee Fund
- ▩ ----- Exam Service

(LBS 2/85)

KSNA

the voice of Nursing in Kansas

*Attn. #7
2-6-1985*

Statement of the Kansas State Nurses' Association
by Executive Director Lynelle King, R.N., M.S.N.
Before the House Public Health and Welfare Committee
February 6, 1985

RE: HB 2082 Various Changes in the powers of the State Board of Nursing

Mr. Chairman and members of the committee, my name is Lynelle King and I represent the Kansas State Nurses' Association, the professional organization for Registered Nurses in Kansas. Obviously, any bill which proposes changes in the regulation of nurses affects our members and KSNA studies such bills carefully.

KSNA supports the state board of nursing in being able to better regulate nurses who hold a license in Kansas and in one or more other states. The provisions of this bill would make clear that the Kansas Board of Nursing may hold a hearing related to the continued licensure of any Kansas licensee who has removal/suspension or limitation of his/her nursing license in another state. The reasons for such loss in another state generally would be relevant to whether or not such a licensee should retain their license in Kansas, also (such as abuse or theft of drugs).

Related to increase in fee limits, I cannot give the KSNA's opinion since our decision-makers have not seen the proposed increases.

Related to the matter of authorizing collection of examination fees by the mentioned "examination service", KSNA would reluctantly agree only on the basis that the "examination service" otherwise would charge more and would result in higher fees for Kansas nurses and/or for the State Board of Nursing.

I will be happy to answer any questions. Thank you for the opportunity to comment.

*Attn. #7
2-6-85*