Approved 2/9/1984
Date

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Marvin Littlejohn
Chairperson
at 1:30 a.m./p.m. on February 8, 1984 in room 423-S of the Capitol.

All members were present except:

Representative Ken King, excused

Committee staff present:

Emalene Correll, Research
Bill Wolff, Research
Norm Furse, Revisor
Sue Hill, Secy. to Committee

Conferees appearing before the committee:

Dr. Robert Harder, Department of SRS.
Ms. Maryanne Estabon, Nat'l Hispanic Council on Aging
Jerry Slaughter, Kansas Medical Society
Ms. Cornelia DeMoff, participant at E. Topeka Senior Center
Ken Schafermeyer, Ks. Pharmacists Association
Harold Riehm, Ks. Assoc Osteopathic
Representative Charles Laird
Mr. William Dean, Merrell Dow Company, Overland Park, Ks.

Visitor's register, (See attachment No. 1. for details).

Chairman called meeting to order, introducing Dr. Harder who gave hand-out to committee members in regard to HB 2761. (See Attachment No.2.)

Hearings began on HB 2761:-

Dr. Harder read from printed testimony, i.e. position of SRS as, the dept. of SRS supports passage of this proposed legislation. The increase in the ulilization of bioequivalent generic drug products will enhance the efficiency of program expenditures without detriment to the quality of services and care provided. He then answered questions from committee, i.e.--language on page 2. line 52 of HB 2761, what type of (plan) are you speaking of; how much money will this bill save the SRS; what percentage of drugs now are substituted with a generic drug, are patients, (purchaser of these drugs in most cases), allowed to refuse the generic drug, etc. Extensive questioning took place.

Maryanne Estabon, Nat'l Hispanic Council on Aging representative gave hand-out to committee, see (Attachment No. 3.), for details. Her group is appalled to see the state of Kansas, create a two tier health care system for Kansas citizens. They feel poor persons are being denied the prescriptions their doctor has prescribed and that substitutions with generic drugs are made without their consent or approval. They are opposed to the amendment of House Bill 2761, specifically lines 052 to 056, and feel these lines should be stricken from the bill and the bill left as it stands now.

Jerry Slaughter, Kansas Medical Society, spoke in opposition to HB 2761, said their organization has strong reservations about parts of it. The present law already gives the physicians and dentists a choice of where to indicate on their prescription form whether or not a brand drug, or generic drug be used. We feel the law should stay the way it is. We feel there should not be a separate set of standards in medication for citizens. We are telling medicare patients they can't have certain drugs and the rest of us (not on medicare) can. I know the SRS needs to cut back and save money, but, don't think that a 2% savings is that significant, for what takes place here. This would serve to take away judgement decisions from physicians when he is the one that knows the patient and knows what drugs he has taken for a long period of time. We ask you to reject this bill. He then answered numerous questions.

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE,

room 423-S, Statehouse, at 1:30 ~~a.m.~~/p.m. on February 8, 1984

HB 2761 continued:

Cornelia DeMoff, participant at East Topeka Senior Center spoke to HB 2761, in that all peoples should have the same choices for their medication. There should not be two levels, one for the poor and disadvantaged, and the other for the rich and healthy. (It may be noted here this printed text is very like Attachment 3.) (See Attachment #4.), for details of her comments. She is against this bill.

Ken Schafermeyer, Ks. Pharmacists Assoc, spoke in support of HB 2761, with one minor change that his group proposes in an amendment. (See Attachment No. 5.), for details. He spoke to several questions that had earlier been posed from committee, i.e., yes the purchaser can request brand name drugs rather than generic, yes, the Food and Drug Administration publication up-dated quarterly has the determination of bio-equivalent drugs, no physician or pharmacists has ever been found to be at fault when a drug has been exchanged for generic, etc.

Further, he stated from a draft of his remarks. (See Attachment No. 6.), for details. A study has revealed that a patient saves about $1.73 per prescription when brand exchange is exercised. This resulted in nearly $6.8 million savings in 1980. He commented at length about the physicians marking the prescription selection "dispense as written", or to use the brand exchange for a bio-equivalent. Stated some statistics, and what other states have discovered along these lines. He said a very simple amendment to HB 2761 would resolve the discrepancy between the Federal regulations and Kansas laws, changing line 45 from language, "Dispense as written", to "brand medically necessary". Line 52, to delete the reference to paragraph 2, making it applicable to medicade prescriptions. (The physician must certify in his own handwriting on the prescription form, "Brand Medically Necessary."

Representative Charles Laird then spoke to HB 2761, it is his view that poor people will get poor drugs. Generic drugs just are not as good as brand name drugs. The FDA are the same folks who brought us EBA and dioxin, so don't put a lot of stock in the FDA. The companies that make generic medicines do not do research, they can have the rights to brand name drugs after 17 years when the patent has expired. I have no interest in drug companies. I am interested in getting good drugs for all people. I know we have to cut budgets, but I don't know that this is the place to do it. He then answered questions from committee.

Mr. Bill Dean, Merrill Dowe Company, stated their company does not make generic drugs, but he is very concerned with the intent of this bill, in that under this plan proposed by SRS mandate that generic drugs on all medicade prescriptions, without the physician to use the drug product the prescriber feels is the correct drug for the diagnosis. He then explained MAC drugs, and answered questions from committee.

Mr. Harold Riehm spoke in opposition to HB 2761.

Hearings on HB 2761 concluded.

Jerry Slaughter then was invited by Chairman to give his testimony on HB 2723. He said briefly his association is in support of HB 2723.

HB 2783 was then brought to attention of committee by Chairman. In reference to line 44, strike word (Loperamide). This is a schedule 5 drug that has been stricken by the FDA, and anytime the Feds strike, then we have to take it off our statutes as well. Asking committee to think about this, then Emalene Correll cited some specifics on technical items in the bill. Rep. Niles then made a motion HB 2783 be passed out of committee favorably and put on consent calendar. Motion seconded by Rep. Green, question called, motion carried.

Meeting adjourned at 3:00 p.m.

Date: 2-8-84 891

GUEST REGISTER

HOUSE

PUBLIC HEALTH AND WELFARE

Please Print

NAME	ORGANIZATION	ADDRESS
KEITH R LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS	TOPEKA
Jack Snively	A.C.C.H.	Perry KS
L. Allsbrook	Menninger School of Psych.	Topeka
Marianne Esteban	Natl Hispanic Council on Aging	Topeka
Jerry Hedrick	Marion Inc	Spring Hill
Jake Boenburg	Louis Ks	
Lucas Cano	East Topeka Sr. Center Topeka Ks	Topeka Ks
Mary J. Brown	East Topeka Comm Action	Topeka, Ks
Willard Whitfield	SRS	Topeka Ks
Bill Pope	KSU	KC

Attm. #1
2-8-1984

Date: 2-8-84 pg 2

GUEST REGISTER

HOUSE

PUBLIC HEALTH AND WELFARE

NAME	ORGANIZATION	ADDRESS
Bill Bain	Johnson Dept	Overland Park, Ks
Harold Riehm	Ks Assn Osteopathic Meds	Topeka
Jerry Slaughter	KS Med Society	Topeka
Rebecca Kupper	KHA	"
Ken Schafermeyer	KS Pharmacists Assn	"
Lynn E. Elwell	Ks. State Board of Pharmacy attorney	
Robert E. Davis	" " " " "	

#2 - 2-8-84

State Department of Social and Rehabilitation Services

Statement Regarding House Bill 2761

I. Short Title of Bill

Generic Drug Dispensing

An amendment to K.S.A. 65-1637 to enhance the potential utilization of bioequivalent generic drug products in programs developed under plans administered by the Secretary of the Department of Social and Rehabilitation Services.

II. Background

K.S.A. 65-1637 of the Kansas Pharmacy Practices Act permits pharmacists in the course of dispensing prescriptions to exercise brand exchange of bioequivalent drug products to achieve a lesser cost to the purchaser. The prescribing practitioner may prohibit brand exchange by indicating the prescription order is to be dispensed specifically as prescribed. An increased incidence of brand exchange and a subsequent reduction in pharmacy program expenditures will occur if the decision to exercise brand exchange is solely that of the dispensing pharmacist.

III. Discussion

Passage of this bill will eliminate the prerogative of the prescribing practitioner to preclude the dispensing pharmacist from exercising brand exchange of bioequivalent drug products. Recipients of pharmacy services under the Kansas Medicaid/MediKan program of the Department of Social and Rehabilitation Services will receive more prescriptions dispensed as bioequivalent generic products resultant of an increase in unrestricted brand exchange initiated by pharmacists. The total expenditures of these programs will be reduced due to the increased utilization of the lower cost generic drug products.

The restriction of brand exchange to products determined bioequivalent by the federal food and drug administration assures that the quality of care received is not less than that provided by use of a brand name product. Pharmacists have the educational background and reference resources available to solely determine the appropriatenes of exercising brand exchange and if consultation with the prescribing practitioner in this regard is indicated.

IV. SRS Position

The Department of Social and Rehabilitation Services supports passage of this proposed legislation. The increase in the utilization of bioequivalent generic drug products will enhance the efficiency of program expenditures without detriment to the quality of services and care provided.

Robert C Harder, Secretary
Office of the Secretary
Social and Rehabilitation Services
296-3271
January 25, 1984

GH:dch
1/25/84
0053I

Attm. #2
2-8-1984

#3 2/8/84

NHCoA

THE NATIONAL HISPANIC COUNCIL ON AGING

1913 Alabaster Dr., Silver Springs, MD 20904

National Hispanic Council on

Aging

Testimony On

House Bill #2761

An Act Concerning Prescriptions For Drugs

Presented To The

House Public Health and Welfare Committee

State Capitol, Room #423 S

Topeka, Kansas

February 8, 1984

Attm. #3
2-9-1984

Good afternoon, Chairman Littlejohn, and members of the House Public Health and Welfare Committee. My name is Mariane Esteban, graduate law student and member of the Topeka Chapter of the National Hispanic Council on Aging. I am here testifying today as a representative of the NHCoA, which is a non-profit organization that serves the advocacy needs of the Hispanic community, specially the elderly and disadvantaged.

One of the goals of the NHCoA is to advocate equal access to the health care system by all American citizens. Consequently, we are appalled to see that the state of Kansas, specially the Secretary of SRS has requested from the House Public Health and Welfare Committee to create a two tier health care system for Kansas citizens. We understand that the SRS Secretary needs to balance his budget, however, we find it rather unjust that SRS should propose two separate and unequal health care systems: one for the disadvantaged, poor and elderly and one for the rich and powerful, in ordere to curb SRS's health care costs.

We are all residents of Kansas regardless of our income and resources. Consequently, we all should have access to the same drugs and medications to heal our bodies. Why should a poor person be denied the prescription that his doctor has perscribed even when he orderss, "Dispense as written" and be substituted with a generic name drug that does not have a proven record of healing, and which might have a dubious quality of care control when manufactured?

We are opposed to the Amendment of House Bill #2761, specifically lines 052 to 056. These lines should be stricken from the Bill and the Bill should be left as it is.

Thank you for the opportunity to present testimony to you. I'll be happy to answer any questions.

#4
2-8-84

EAST TOPEKA COUNCIL ON AGING, INC.

1101 East 10th Street Topeka, Kansas 66607

913 232-7765

EAST TOPEKA COUNCIL ON AGING

TESTIMONY ON

HOUSE BILL #2761

AN ACT CONCERNING PRESCRIPTIONS FOR DRUGS

PRESENTED TO THE HOUSE

PUBLIC HEALTH AND WELFARE COMMITTEE

STATE CAPITOL, ROOM #423 S

TOPEKA, KANSAS

FEBRUARY 8, 1984

1:30 P.M.

Attm. #4
2-8-1984

EAST TOPEKA COUNCIL ON AGING, INC.

1101 East 10th Street Topeka, Kansas 66607

913 232-7765

GOOD AFTERNOON, CHAIRMAN LITTLEJOHN, AND MEMBERS OF THE HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE. MY NAME IS CORNELIA DEMOSS AND I AM A MEMBER OF THE EAST TOPEKA COUNCIL ON AGING. I AM HERE TESTIFYING TODAY AS A REPRESENTATIVE OF THE E.T.C.O.A. WHICH IS A NON-PROFIT ORGANIZATION THAT SERVES THE NEEDS OF THE COMMUNITY, ESPECIALLY THE ELDERLY.

IT IS UNJUST THAT SRS SHOULD PROPOSE TWO SEPARATE AND UNEQUAL HEALTH CARE SYSTEMS: ONE FOR THE DISADVANTAGED, POOR AND ELDERLY AND ONE FOR THE RICH AND POWERFUL, IN ORDER TO BALANCE THE SRS BUDGET.

WE ARE ALL RESIDENTS OF KANSAS REGARDLESS OF OUR INCOME AND RESOURCES. WE ALL SHOULD HAVE ACCESS TO THE SAME DRUGS AND MEDICATIONS TO HEAL OUR BODIES. WHY SHOULD A POOR PERSON BE DENIED THE PRESCRIPTION THAT HIS DOCTOR HAS PRESCRIBED? WHY SHOULD THE PRESCRIBED MEDICATION BE SUBSTITUTED WITH A GENERIC NAME DRUG THAT DOES NOT HAVE A PROVEN RECORD OF HEALING.

WE ARE OPPOSED TO THE AMENDMENT OF HOUSE BILL #2761, SPECIFICALLY LINES 052 TO 056.

THANK YOU FOR THE OPPORTUNITY TO PRESENT TESTIMONY TO YOU.

#5
2-8-4

DRAFT

THE KANSAS PHARMACISTS ASSOCIATION
1308 WEST 10TH
PHONE (913) 232-0439
TOPEKA, KANSAS 66604

KENNETH W. SCHAFERMEYER, M.S., CAE
PHARMACIST
EXECUTIVE DIRECTOR

STATEMENT TO HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE

FEBRUARY 8, 1984

SUBJECT: HOUSE BILL 2761 REGARDING BRAND EXCHANGE

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

MY NAME IS KEN SCHAFERMEYER AND I AM EXECUTIVE DIRECTOR OF THE KANSAS PHARMACISTS ASSOCIATION--AN ORGANIZATION REPRESENTING APPROXIMATELY 80% OF THE PRACTICING PHARMACISTS IN THE STATE OF KANSAS. I APPRECIATE THE OPPORTUNITY TO ADDRESS YOU ON HOUSE BILL 2761 REGARDING INCREASED OPPORTUNITIES FOR BRAND EXCHANGE.

THE PROBLEM

AS YOU KNOW, THE COSTS OF HEALTH CARE HAVE INCREASED DRAMATICALLY OVER THE PAST SEVERAL YEARS. NEITHER THE GOVERNMENT NOR THE PUBLIC CAN AFFORD THESE COSTS WHICH SEEM TO DOUBLE EVERY THREE OR FOUR YEARS. AS YOU KNOW, THERE HAVE BEEN MANY ATTEMPTS TO CONTROL COSTS OF HEALTH CARE SERVICES. SOME OF THESE EFFORTS HAVE BEEN SUCCESSFUL WHILE OTHERS HAVE NOT.

ONE COST CONTAINMENT EFFORT WHICH HAS BEEN SUCCESSFUL IS BRAND EXCHANGE. BECAUSE OF A RECENT CHANGE IN KANSAS LAW, PHARMACISTS MAY NOW SELECT LOWER COST GENERIC EQUIVALENTS FOR

Attm. #5
2-8-1984

MANY PRESCRIPTIONS. ONE STUDY CONDUCTED BY THE UNIVERSITY OF KANSAS INDICATED THAT PATIENTS SAVED ABOUT $1.73 PER PRESCRIPTION WHEN BRAND EXCHANGE IS EXERCISED. THIS RESULTED IN ABOUT $6.8 MILLION OF SAVINGS IN 1980. THIS IS THE ONLY STUDY DONE IN KANSAS AND WAS CONDUCTED A LITTLE OVER A YEAR AFTER THE BRAND EXCHANGE LAW FIRST WENT INTO EFFECT. IT IS REASONABLE TO ASSUME THAT THE AMOUNT OF BRAND EXCHANGE HAS INCREASED DRAMATICALLY SINCE THEN AND SAVINGS HAVE INCREASED ACCORDINGLY. THERE ARE, HOWEVER, NO RECENT STUDIES TO DETERMINE THE EXACT AMOUNT.

THE SAME STUDY ALSO SHOWED THAT IN 1980 PHYSICIANS REDUCED THE NUMBER OF OPPORTUNITIES FOR BRAND EXCHANGE BY 21.9% BY SIMPLY SIGNING THE PRESCRIPTION FORM ON THE LINE WHICH INDICATED "DISPENSE AS WRITTEN." BY THE PHYSICIAN SIGNING ON THIS LINE, KANSAS LAW PREVENTS BRAND EXCHANGE. PHYSICIANS HAVE LEARNED THAT BRAND EXCHANGE CAN RESULT IN SIGNIFICANT COST SAVINGS TO THE PATIENT WHILE GUARANTEEING A HIGH QUALITY OF CARE. WHILE PHYSICIANS PREVENT BRAND EXCHANGE ON FEWER OCCASIONS NOW, MANY PHYSICIANS STILL PREVENT BRAND EXCHANGE AS A MATTER OF ROUTINE.

DR. HARDER AND HIS STAFF AT SRS HAVE BEEN LEADERS IN HEALTH CARE COST CONTAINMENT IN KANSAS. ONE OF THE FEW AREAS OF THE MEDICAID BUDGET WHICH HAS BEEN UNRESPONSIVE TO COST CONTROLS ~~HAS~~ IS THE MANUFACTURER'S PORTION OF DRUG COSTS WHICH PHARMACISTS MUST PASS ON TO THE MEDICAID PROGRAM. WHILE BRAND EXCHANGE HAS RESULTED IN SIGNIFICANT SAVINGS, THESE SAVINGS COULD BE INCREASED IF PHYSICIANS DID NOT ROUTINELY PREVENT DRUG PRODUCT SELECTION.

ANOTHER PROBLEM WITH THE CURRENT KANSAS BRAND EXCHANGE LAW IS THAT FEDERAL REGULATIONS FOR THE MAXIMUM ALLOWABLE COST (MAC) PROGRAM ARE NOT IN AGREEMENT WITH KANSAS LAW. THE FEDERAL MAC REGULATIONS STIPULATE THAT MEDICAID MAY NOT REIMBURSE PHARMACISTS FOR MORE THAN A SPECIFIED PRICE (WHICH IS BASED ON GENERIC PRICES RATHER THAN BRAND NAME PRICES) UNLESS THE PHYSICIAN INDICATES IN HIS OWN HANDWRITING THAT, IN HIS MEDICAL JUDGMENT, A SPECIFIC BRAND IS NECESSARY FOR A PARTICIULAR RECIPIENT. THE U. S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE (WHICH IS NOW REFERRED TO AS THE DEPARTMENT OF HEALTH AND HUMAN SERVICES) ISSUED A MEMO TO STATE AGENCIES ADMINISTERING MEDICAID PROGRAMS ON MARCH 26, 1980 WHICH INTERPRETED THE FEDERAL MAC REGULATIONS. EACH MEMBER OF THE COMMITTEE HAS RECEIVED A COPY OF THIS MEMO AND I WOULD LIKE TO REVIEW A FEW HIGHLIGHTS WITH YOU. I THINK YOU WILL AGREE THAT THE POINTS MADE IN THIS MEMO APPLY VERY WELL TO THE CURRENT SITUATION IN KANSAS. (See memo from HEW)

TO DEMONSTRATE THE FACT THAT SIGNING A NAME ON A PARTICULAR LINE ON THE PRESCRIPTION BLANK BECOMES A MATTER OF HABIT RATHER THAN A CONSCIOUS DECISION, I HAVE PROVIDED EACH MEMBER OF THE COMMITTEE WITH FOUR EXAMPLES OF PRESCRIPTIONS FILLED BY A TOPEKA PHARMACY IN THE LAST FEW DAYS. THE NAMES OF THE PATIENT, PHYSICIAN AND PHARMACY HAVE BEEN DELETED TO PROTECT CONFIDENTIALITY. PRESCRIPTIONS ONE AND TWO ARE PRESCRIPTIONS WRITTEN GENERICALLY--NO BRAND NAME IS SPECIFIED. NEVERTHELESS, THE PHYSICIAN SIGNED THE PRESCRIPTION BLANK ON THE "DISPENSE AS WRITTEN" LINE. PRESCRIPTIONS

THREE AND FOUR ARE SIGNED ON THE "BRAND EXCHANGE PERMISSIBLE" LINE EVEN THOUGH THEY ARE WRITTEN FOR SINGLE SOURCE BRAND NAME DRUGS--THERE ARE NO GENERIC EQUIVALENTS TO DISPENSE.

THE SOLUTION

A VERY SIMPLE AMENDMENT TO HOUSE BILL 2761 WOULD RESOLVE THIS DISCREPANCY BETWEEN FEDERAL REGULATIONS AND KANSAS LAWS AND WOULD RESULT IN INCREASED SAVINGS TO THE KANSAS MEDICAID PROGRAM. OUR SUGGESTIONS FOR THE AMENDED BILL HAVE ALSO BEEN GIVEN TO EACH COMMITTEE MEMBER. PLEASE NOTE THAT THERE ARE ONLY TWO CHANGES--LINE 45 CHANGES "DISPENSE AS WRITTEN" TO "BRAND MEDICALLY NECESSARY" AS SPECIFIED IN THE FEDERAL MAC REGULATIONS. LINE 52 HAS BEEN CHANGED TO DELETE THE REFERENCE TO PARAGRAPH TWO THEREBY MAKING THIS PARAGRAPH APPLICABLE TO MEDICAID PRESCRIPTIONS. IN OTHER WORDS, FOR THE PHYSICIAN TO PREVENT BRAND EXCHANGE FOR MEDICAID PRESCRIPTIONS, HE MUST CERTIFY IN HIS OWN HANDWRITING ON THE PRESCRIPTION FORM "BRAND MEDICALLY NECESSARY."

I HAVE ANTICIPATED THAT SEVERAL QUESTIONS WOULD OCCUR AND I WOULD LIKE TO ANSWER THEM AT THIS POINT.

Q 1. WILL THIS BE AN UNDUE INCONVENIENCE FOR THE PHYSICIAN?

ANSWER: NO. THE PHYSICIAN WILL MERELY BE REQUIRED TO WRITE THREE WORDS ON A PRESCRIPTION BLANK RATHER THAN AUTOMATICALLY SIGNING ON A PARTICULAR LINE. IT IS VERY INCONVENIENT, HOWEVER, FOR THE PHARMACIST TO BE REQUIRED BY STATE LAW TO DISPENSE A BRAND NAME DRUG BUT BE REIMBURSED ONLY FOR A GENERIC DRUG.

THE PHARMACIST HAS A CHOICE OF TAKING A LOSS ON THE PRESCRIPTION OR TRYING TO CONTACT THE PHYSICIAN TO CHANGE THE PRESCRIPTION ORDER WHILE THE PATIENT IS WAITING.

ALSO, ALMOST ALL HOSPITALS USE A GREAT DEAL OF GENERICS BECAUSE OF A LIMITED FORMULARY OF DRUGS WHICH ARE STOCKED AND DISPENSED. PHYSICIANS PRACTICING IN THESE HOSPITALS OFTEN HAVE NO RIGHTS TO SELECT PARTICIPAR BRAND NAME DRUGS. GENERICS ARE EXCHANGED FOR BRAND NAMES ROUTINELY DESPITE THE FACT THAT THE PHYSICIAN MAY SPECIFY A BRAND NAME DRUG. THIS IS STANDARD POLICY IN MOST HOSPITALS.

Q 2. WHY CHANGE THE WORDING "DISPENSE AS WRITTEN" TO "BRAND MEDICALLY NECESSARY"?

ANSWER: THIS SPECIFIC WORDING IS REQUIRED BY FEDERAL REGULATIONS AND CAN BECOME WIDELY KNOWN TO PHARMACISTS AND PHYSICIANS BEFORE A JULY 1 IMPLEMENTATION DATE OF THE BILL.

Q 3. WHAT ABOUT AN ORAL PRESCRIPTION?

ANSWER: FEDERAL AND STATE LAWS ALREADY REQUIRE THAT SOME PRESCRIPTIONS BE WRITTEN, RATHER THAN ORAL. PHARMACISTS AND PHYSICIANS HAVE BECOME USED TO ACCEPTING ORAL PRESCRIPTIONS FOR SCHEDULE II CONTROL SUBSTANCES WHEN NECESSARY, PROVIDED THAT A WRITTEN PRESCRIPTION BE SENT TO THE PHARMACY AND FILED. IF A PHYSICIAN FEELS THAT A PARTICULAR BRAND NAME DRUG IS MEDICALLY NECESSARY, IT WOULD BE EASY FOR HIM TO WRITE A PRESCRIPTION FOR THE PHARMACY'S FILES. NOTHING WOULD PREVENT THE PHYSICIAN FROM TELEPHONING A PRESCRIPTION ORDER.

Q 4. HAS BRAND EXCHANGE REALLY SAVED THAT MUCH MONEY?

ANSWER: STUDIES DONE IN SOME STATES WITHIN A YEAR OF THE IMPLEMENTATION OF BRAND EXCHANGE LAWS HAVE ~~NOT~~ SHOWN THAT THE POTENTIAL OF DRUG PRODUCT SELECTION IS NOT MET IN THE FIRST YEAR--SUBSEQUENT STUDIES SHOW THAT THE LEVEL OF BRAND EXCHANGE INCREASES WITH TIME. STUDIES IN SOME STATES DO NOT APPLY TO KANSAS BECAUSE BRAND EXCHANGE LAWS VARY WIDELY FROM STATE TO STATE. WITH FIVE YEARS OF EXPERIENCE IN BRAND EXCHANGE IN KANSAS, HOWEVER, WE CAN SEE THAT THERE HAVE BEEN SIGNIFICANT COST SAVINGS.

Q 5. SHOULD THIS AMENDMENT APPLY ONLY TO MEDICAID PRESCRIPTIONS OR TO ALL PRESCRIPTIONS?

ANSWER: THE ISSUE BEING ADDRESSED WITH THIS BILL INVOLVES MEDICAID PRESCRIPTIONS ONLY. THE PROPOSAL WOULD SERVE THE DUAL PURPOSE OF SAVING SRS MONEY WHILE RESOLVING A PROBLEM PHARMACISTS ARE HAVING WITH A CONFLICT BETWEEN STATE AND FEDERAL LAWS. SINCE THIS PROVISION IS IN COMPLIANCE WITH THE FEDERAL MAC REGULATIONS, IT IS DOUBTFUL THAT THERE WOULD BE ANY VIOLATION OF THE EQUAL SERVICES PROVISION OF THE FEDERAL TITLE XIX GUIDELINES. NEVERTHELESS, MEDICAID PRESCRIPTIONS ACCOUNT FOR LESS THAN ONE-TENTH OF ALL THE PRESCRIPTIONS IN THE STATE OF KANSAS AND THIS COMMITTEE MAY WANT TO EXTEND THESE COST SAVINGS TO THE GENERAL PUBLIC.

Q 6. HOW MUCH WOULD THIS PROVISION SAVE?

ANSWER: SINCE THE FEDERAL GOVERNMENT HAS ESTABLISHED THE MAXIMUM ALLOWABLE COST PROGRAM FOR MEDICAID PRESCRIPTIONS, MUCH OF

THE COST SAVINGS IS ALREADY BEING REALIZED. HOWEVER, MAC DOES NOT APPLY TO ALL MULTI-SOURCE DRUGS. ALTHOUGH WE HAVE NOT CALCULATED THE TOTAL COST SAVINGS ~~FROM~~ FOR THIS MEASURE, INCREASED BRAND EXCHANGE FOR TWENTY DRUG PRODUCTS WOULD SAVE THE STATE OF KANSAS APPROXIMATELY $300,000.00. HOWEVER, LATER THIS YEAR AT LEAST THREE MAJOR DRUG PRODUCTS WILL GO OFF PATENT AND COST SAVINGS FOR THESE DRUGS ALONE MAY SAVE AN ADDITIONAL $300,000.00. INCREASED BRAND EXCHANGE TO THE GENERAL PUBLIC, HOWEVER, WOULD SAVE MANY TIMES THIS AMOUNT SINCE THESE SAVINGS WOULD AFFECT TEN TIMES AS MANY PRESCRIPTIONS AND ABOUT FIFTY MORE OF THE MOST COMMONLY USED MULTI-SOURCE DRUGS. WHILE WE HAVE NOT ESTIMATED THE COST SAVINGS TO THE GENERAL PUBLIC FROM THIS PROVISION, SAVINGS WOULD BE AT LEAST SEVERAL MILLION DOLLARS PER YEAR.

THANK YOU VERY MUCH FOR THE OPPORTUNITY TO ADDRESS YOU ON THIS ISSUE. KPhA STANDS READY TO ASSIST IN THE CONTROLLING OF HEALTH CARE COSTS AND IMPROVEMENT OF HEALTH CARE QUALITY AT ANY TIME. THANK YOU.

Attm #6
2-8-84

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Health Care Financing Administration
Baltimore, Maryland 21235

INFORMATION MEMORANDUM
HCFA-IM-80- 9 (BPP)
March 26, 1980

TO: STATE AGENCIES ADMINISTERING MEDICAID PROGRAMS

SUBJECT: Title XIX, Social Security Act: Physician Certification to Override Maximum Allowable Cost Limits on Prescribed Drugs

REGULATION REFERENCE: 42 CFR 447.332(b) (originally 45 CFR 250.30); SRS-AT-75-72 (MSA), August 15, 1975; IM-77-25 (MSA), May 26, 1977; HCFA-IM-77-39 (HCFA), July 18, 1977

ATTACHMENT: Review and clarification of policies regarding physician override of Maximum Allowable Cost limits

INQUIRIES TO: Regional Medicaid Directors

Leonard D. Schaeffer
Administrator

Attm. #6
2-8-1984

As stated in 42 CFR 447.332(b); "Exception: Certification of brand name drugs. (1) The cost of a multiple source drug is not limited to the MAC if a physician certifies in his own handwriting that, in his medical judgment, a specific brand is medically necessary for a particular recipient." This provision has been the topic of considerable discussion by pharmacy administrators as to what should constitute proper compliance with respect to the form of certification and the procedures to be followed. The regulations at section 447.332(b) address two specific issues in this regard. First, "(3) A check-off box on a form is not acceptable, but a notation like 'brand necessary' is allowable." Second, "(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HEW." The prohibition on check-off boxes reinforces the principle that the provision for a MAC override is not included as a mere convenience regardless of the medical necessity. Rather it is intended that the prescriber perform more than a simple motion to demonstrate that he has made a conscious medical judgment that a particular brand is medically necessary for a particular patient. The provision regarding the location of the actual certification documents demonstrates that while the agencies have leeway in implementation, there must be written documentation and that it must be available for inspection.

Information Memorandums IM-77-25 (MSA) and HCFA-IM-77-39 (MMB) discussed further and reinforced the principle of conscious handwritten certification. IM-77-25 reiterated the unacceptability of a check-off box and stated that rubber stamp certifications are likewise unacceptable. IM-7-39 states that the use of dual-line prescription forms (signature on one line permits substitution, signature on the other line prevents substitution) was not sufficient for the purposes of the MAC program. It was recognized that some State laws permit simple methods to prevent substitution but laws such as these allow physicians to prevent substitution for non-medical reasons. The override of a MAC limit must be based solely on medical judgment and, therefore, there is a requirement to certify that there is a medical reason for any override. This certification is purposely designed to avoid habituation to simple methods of avoiding substitution. In most cases acceptable Federal wording such as "brand necessary" (or preferably "brand medically necessary will also be sufficient to meet the requirements of State law. State agencies could perform a valuable service by pointing out this fact to prescribers so that they are aware that they can follow the identical procedure for all patients if they wish. This point should not be dismissed lightly since the Federal wording may be more in keeping with the intent of state overrides (i.e., when the State override was intended to be used for medical reasons) than simple acts that can easily become casual habits rather than conscious decisions.

3

The need for a certification procedure which is more than a reflex motion can be seen in a comparison of Michigan and New York. In New York where a simple dual signature form is used, 75 percent of all prescriptions are signed on the "do not substitute" line. This occurs for single-source drugs which have no substitutes as well as multi-source drugs. In Michigan where the prescriber must write out the phrase, "do not substitute", only four to five percent of the prescriptions are restricted. It is highly unlikely that New York prescribers are so radically different in their medical concerns regarding substitution. It is equally unlikely that Michigan prescribers would fail to write out their restriction when they feel there is a medical reason to bar substitution. A more likely explanation is that the dual-line prescription form is so simple that it no longer requires a conscious recognition of the consequences of the act of signing. The New York example demonstrates that requiring a prescriber to write out a phrase results in a significant difference in the cost of drugs to the State and Federal governments as well as to private citizens. Conversely barring substitution by means of reflex procedures undermines the intent of State product selection laws and the Federal MAC program.

Several divergent approaches have been employed by States to implement the physician certification provision. One state has by law eliminated any override, one state has issued special forms to prescribers to be attached to prescriptions (example of Nebraska form attached), and another state has included MAC overrides in its prior approval system. These are innovative and acceptable methods, as is the more common approach of having a suitable phrase written on the face of the prescription.

In summary, the provision for physician override of MAC limits is intended solely as a mechanism to allow for a medical judgement that a particular brand that is more costly is medically necessary for a particular patient. Procedures used to implement this provision should not compromise this intent into a convenient way to circumvent the MAC program. Check-off boxes, dual-line prescription forms, rubber stamps and initialed notations (e.g., "D.A.W." - dispense as written, "N.S." - no substitution, etc.) are all measures to avoid substitution through use of simple actions which can easily become habitual. These are all unacceptable for MAC overrides.

4

PRESCRIPTIONS WRITTEN GENERICALLY

Rx 1

Date 2/3/81

10% Sulfacetamide

drops 3 per eye q.i.d.

Label All Prescriptions
No Refill
_____ Unless Indicated
_____ Times or Until

Dispense as Written [redacted]

Brand Exchange Permissable _______________ M.D.

BNDD AY1301338

Rx 2

ADDRESS _______________ DATE 3 Feb 79

℞

Tetracycline 250 [redacted]

No. 24

Sig cap i tid pc

☑ LABEL

REFILL _____ TIMES

[redacted] , M.D. — DISPENSE AS WRITTEN

_______________ , M.D. — BRAND EXCHANGE PERMISSIBLE

PRESCRIPTIONS FOR SINGLE-SOURCE DRUGS

WRITTEN BY BRAND NAME

Rx 3

Address _____

℞

Anaprox 275mg ☆ ii initially then
☆ tab q 6-8 hrs. prn #20

LABEL ☑
REFILL ☑ 2
DEA No. _____

_____ M.D.
DISPENSE AS WRITTEN

M.D.
BRAND EXCHANGE PERMISSIBLE

Rx 4

Date 2/1/84

Cogentin 1mg ocb ·0653
#100
Sig 1 tid

refill as needed

EASE LABEL FULLY

_____ M.D.
Dispense As Written

Brand Exchange Permissible

Session of 1984

HOUSE BILL No. 2761

By Committee on Public Health and Welfare

1-24

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

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

Section 1. K.S.A. 65-1637 is hereby amended to read as follows: 65-1637. In every store, shop or other place defined in this act as a "pharmacy" there shall be a registered pharmacist in charge and the compounding and putting up of prescriptions shall be limited to registered pharmacists only. Except as otherwise provided by the pharmacy act of this state, when a pharmacist is not in attendance at a pharmacy, the premises shall be enclosed and secured. Prescription orders may be written, oral or telephonic. Blank forms for written prescription orders may have two signature lines. The first signature line shall state: "Dispense as written _____." The second signature line shall state: "Brand exchange permissible _____." Prescriptions shall only be filled or refilled in accordance with the following requirements:

(a) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except that a pharmacist who receives a prescription order for a brand name drug product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

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

(2) the prescriber, in the case of a prescription signed by the prescriber, writes in ~~his or her~~ *the prescriber's* own handwriting "dispense as written" on the prescription, or

"brand medically necessary"

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

(4) the federal food and drug administration has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication.

(b) The provisions of paragraphs (1), (2) and (3) of subsection (a) shall not be applicable if the prescribed drugs are being dispensed under a plan developed by the secretary of social and rehabilitation services pursuant to subsection (s) of K.S.A. 39-708c and amendments thereto.

~~(b)~~ *(c)* Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the physician shall bear the name of the person so telephoning. Nothing in this paragraph shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

~~(c)~~ *(d)* No prescription shall be refilled, if it contains a statement that it is not to be refilled.

~~(d)~~ *(e)* If any prescription order contains a provision that the prescription may be refilled a specific number of times within or during any particular period, such prescription shall not be refilled except in strict conformity with such requirements.

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

~~(f)~~ *(g)* Any pharmacist who exercises brand exchange and dispenses a less expensive drug product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug.

Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in ~~his or her~~ *the pharmacist's* professional judgment and

discretion such pharmacist is of the opinion that it should not be filled or refilled.

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

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

(1) and (3)