Approved: 4-2-93
Date

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chairperson Joann Flower at 1:30 p.m. on March 31, 1993 in Room 423-S of the Capitol.

All members were present except:

Committee staff present: Emalene Correll, Legislative Research Department
William Wolff, Legislative Research Department
Norman Furse, Revisor of Statutes
Sue Hill, Committee Secretary

Conferees appearing before the committee:
Harold Riehm, Executive Director, Kansas Association of Osteopathic Medicine
Myrle Myers, Co-Chair of Pharmaceutical Manufacturers Association Task Force, Topeka,Ks.
Commissioner Epps, Income Support/Medical Services, Department of SRS
Bob Williams, Executive Director, Kansas Pharmacists Association
Brad Smoot, Pfizer Pharmaceuticals

Written testimony only provided by Doris E. Newman, President, Kansas Chapter of Arthritis Foundation

Others attending: See attached list

Chairperson Flower called the meeting to order drawing attention to Committee minutes for March 16,17,18, 22, 23. She requested that members notify the secretary of any corrections by 5:00 p.m. tomorrow, April 1. If there are no corrections called to the attention of the secretary, these minutes will be approved as presented.

Chair drew attention to the agenda, and requesting a staff briefing on SB 410.

Ms. Correll gave a comprehensive explanation of SB 410, as amended by the Senate Committee on Public Health and Welfare. She drew attention to new language, noting statutorily a new agency would be created to administer the Drug Utilization Review (DUR) related to the Medicaid program. She outlined language that relates to the seven member Board; noted terms of Board members will be staggered so terms will not all expire at the same time. She drew attention to new Sec. (c) on page 4, an amendment to SB 410, by the Senate Committee on Public Health and Welfare . Ms. Correll noted the Committee would need to give consideration to clarifying language in SB 410 as to whether or not the Board members would be paid and would receive (or not receive) subsistence.

CHAIR OPENED HEARINGS ON SB 410.

Harold Riehm, Executive Director, Kansas Association Osteopathic Medicine, offered hand out, (Attachment No. 1). He stated support for SB 410, noted this legislation was not requested by their Association, but he speaks in support of SB 410, not any other legislation as might be amended into it. He gave background on the Drug Utilization Review Committee . The DUR Committee is under the authority of tthe Department of SRS. He detailed procedure requirements being broadened for the Drug Utilization Review Board. He particularly applauded the provision that an osteopathic physician be placed on the Board; he stated support as well, for the "sunshine" provision, and except for exceptions noted, their Association agree that the meetings of the Board, be open meetings.

Approved: 4-2-93
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Myers, Pharmaceutical Manufacturers Association, offered hand out, (Attachment No.2). She noted under the federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90), the federal regulations require each state to have in place this year a drug utilization review board to assist the state by providing educational information on drug usage and by conducting prospective and retrospective utilization review. Currently SRS operates a Drug Utilization Review Committee. SB 410 amends existing statutes dealing with that Committee. She drew attention to a new exception to the Kansas open meeting law in SB 410 so that the DUR Board would not be subject to that law when considering patient profile information or matters relating to identifiable providers. She noted SB 410 does not restrict either the DUR Board nor SRS from making recommendations or decisions on drug therapy. She urged support.

Commissioner Robert Epps, Department of SRS, offered hand out, (Attachment No. 3) He voiced opposition to SB 410, because it duplicates and inappropriately adds requirements to the OBRA 90 that governs the Kansas Drug Utilization Review Program. He outlined the functions of the Review Board, noting the members are paid $100 a meeting plus fees for travel and subsistence. The key purpose of the DUR is to provide the decision makers within SRS, unbiased and objective medical and pharmaceutical recommendations on a variety of issues. The decisions then are made by the Department of SRS, not the Review Board. The Department views it essential that the meetings of the DUR Board are conducted in an unbiased, and objective atmosphere, free of marketing and advertising, providing a sound source of information in which to base the recommendations. He stated inappropriate influences by pharmaceutical sales and marketing personnel on the SRS Medicaid decision-making process would undoubtedly increase costs. He noted the meetings are not closed. Individuals can petition to attend and are most often accommodated in this respect. He noted, however, at most meetings they do not have guests or observers, but they are not restricted.

Bob Williams, Executive Director, Kansas Pharmacists Association, offered hand out (Attachment No. 4). He stated opposition to SB 410. He noted currently the DUR Committee has more members than recommended in SB 410. He detailed responsibilities of the DUR Committee. He stated, if Kansas did not have a DUR program, the Kansas Pharmacists Association could better understand the need for this legislation, however, since there is an established Committee, they view this legislation as unnecessary. He drew attention to federal guidelines in handout; a DUR annual report; DUR newsletter; DUR evaluation Committee roster. He stressed the importance of the Committee to maintain unbiased, objective opinions, when giving ideas and opinions to state government. He stressed, the DUR Committee does not set policy, this is done at the SRS level. SRS meetings are open to the public and this is where policy decisions are made. He then suggested, if it is the consensus of this Committee that the Advisory Committee meetings be opened to the public, and SB 410 is amended in this manner, then all Advisory Committee meetings should be placed under the same regulations.

Mr. Williams introduced Mr. Miller.

Mr. Roger Miller noted he is a pharmacist, and has served 17 years as a representative of the Kansas Pharmacy Foundation, which is composed of past Presidents of the Kansas Pharmacists Association. He stated he has seen the DUR Committee evolve as a responsible and efficient Committee. He stated the Committee is in current compliance with federal law. He detailed responsibilities and duties carried out by the Committee. He noted the subsistence spoken of earlier, in reality means, pizza or a sandwich served during discussions at lunch. He stated he sees no need for legislative action in regard to these issues discussed in SB 410. He noted there is ample input from pharmaceutical manufacturers, there currently are two members on the Committee that are in Research at the University of Kansas Medical Center that provide ample data, and for those reasons, he is opposed to SB 410. (Mr. Miller did not provide written testimony).

Brad Smoot, Pfizer Pharmaceuticals, stated he would provide written testimony later to members. He drew attention to an Attorney General's opinion declaring the DUR is subject to open meetings. He noted there is a letter from the Department questioning the validity of that opinion. It was noted this opinion from the Attorney General's office is only an advisory opinion, and is not binding. He related disputes that occurred during the Hayden Administration when a decision made by the Department of SRS recently to remove widely used products from the state Medicaid formulary. He explained this decision was quietly done, physicians and patients alike were unaware this development was taking place. Many physicians were irate with this directive. Medicine for arthritis, ulcer, head lice, many other drugs were removed from this formulary, and as a result of numerous complaints, these drugs were again returned to the schedule. He stated, had an open meetings ruling been allowed, this kind of a problem would probably not have occurred.

Mr. Smoot drew attention to a letter that had been provided by Ms. Doris Newman, President of Arthritis Foundation, Kansas Chapter that substantiates the situation detailed by Mr. Smoot. See (Attachment No. 5)

Chair opened the meeting to questions from members of conferees.

Numerous questions were asked, i.e., individuals can petition to attend meetings one-two weeks prior to meetings; the DUR Committee feels it is important to know who is requesting attendance at the meetings; there is no fiscal note, however, it was noted the pharmacy category in the SRS budget is the fastest growing; Commissioner Epps stated, the decisions and advice of the Committee might be more subject to influence by the pharmaceutical industry, if there are pharmaceutical representatives present at these meetings. Commissioner Epps stated this could eventually have a possible impact on decisions made by the Committee. He noted the Department of SRS relies very heavily on the recommendations made by the DUR Board.

Mr. Eugene Stephensen, Pharmacists specialist for the Department of SRS was available to answer questions from Committee members. He detailed the rebate program to the state with manufacturers of pharmaceuticals under contract with Kansas. Commissioner Epps stated he didn't feel open meetings would significantly affect the rebate program.

There were questions regarding the selection of the Committee. It was noted the state of Maryland has a similar situation as that of Kansas regarding meeting procedures; it was noted the Attorney General enforces the law, sets policy, relating to an appeal in this kind of a situation; it was noted some members had been contacted by pharmacists that related concerns regarding decisions made by the Department of SRS to approve of some medications and to disapprove of others has actually driven costs higher.

Commissioner Epps replied there was an open meeting held by the Department of SRS on the decision made a few years ago to withdraw some drugs from the formulary. There currently are monthly open meetings held by the Department of SRS, the first Tuesday of every month, which is known throughout the state. These meetings have been held for years. The decision making process by the Department of SRS is conducted in an open forum. There were concerns by some members there is perhaps an underlying problem that causes the differences of opinion on the open meetings for the DUR Committee. It was noted perhaps the agenda for these meetings might perhaps be done in a better manner when notification to the public is made. Pharmaceutical Manufacturers can call to inquire what drugs will be discussed at the meetings, and would probably be granted an invitation to those meetings. There was discussion regarding the honarium paid to members of this Commission by the Department of SRS.

Chair adjourned the meeting 10:19 p.m.

Next Committee meeting time is unknown at this time.

Kansas Association of Osteopathic Medicine

Harold E. Riehm, Executive Director

1260 S.W. Topeka Blvd.
Topeka, Kansas 66612
(913) 234-5563
(913) 234-5564 Fax

March 31, 1993

Testimony on SB 410

To: Chairperson Flower and Members, House Public Health Committee

From: Harold E. Riehm, Executive Director, Kansas Association of Osteopathic Medicine

Thank you for this opportunity to testify on S. B. 410. We appear in support of the Bill. We think it clarifies and makes more specific the responsibilities of the drug utilization review program, and the review board specifically structured to carry out those responsibilities.

In Section 1 (a) of the Bill, we think any study of utilization, be it over or under utilization, would reach conclusions on both. Though prior authorization is not specifically addressed, we see nothing in the enumerated responsibilities of the program that would preclude this as a topic of analysis. It is, of course, a matter about which those I represent have continuing concerns. We also note that in Section 3 (c), the program is required to provide for both prospective and retrospective drug utilization review as specified in OBRA 1990.

We particularly support the structuring of membership on the medicaid drug utilization review board, provided for in New Sec. 2 of the Bill. This will be the board responsible for implementing the studies and formulating the recommendations to SRS. While there may be some interest in increasing consumer representation on the board, we think the provided balance between prescribing providers and representatives of pharmacy (practicing and academic) has merit. We particularly applaud the specific provision that there be an osteopathic physician on the board. While there currently is a D.O. on the DUR, this has not always been the case.

Finally, we support the provision found in New Sec. 2 (b) (f), which we interpret to be a "sunshine" provision. Except for the exception noted, this will require that meetings of the board be open meetings in which interested parties may observe the deliberation process. We see little reason, again, except as noted, why this should not be the case.

Thank you. I will be pleased to respond to questions the Committee may have.

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STATEMENT OF THE
PHARMACEUTICAL MANUFACTURERS ASSOCIATION
BEFORE THE
HOUSE COMMITTEE ON PUBLIC HEALTH & WELFARE
SENATE BILL 410

March 31, 1993
Topeka, Kansas

Madam Chair and members of the Committee. My name is Myrle Myers and I am appearing before you today in my capacity as Co-Chair of the Pharmaceutical Manufacturers Association (PMA) Task Force in Kansas.

PMA is a nonprofit scientific trade association representing more than 100 research-based pharmaceutical companies that are responsible for nearly all the new prescription medications researched, developed and produced in this country.

PMA appreciates this opportunity to testify on Senate Bill 410 which concerns drug utilization review (DUR). Under the federal Omnibus Budget Reconciliation Act of 1990 (known as OBRA 90) and the federal regulations set down last fall, each state is to have in place this year a drug utilization review board to assist the state by (1) providing educational information on drug usage and by (2) conducting prospective and retrospective utilization review.

SRS currently operates a DUR Committee. Senate Bill 410 amends the existing statute dealing with that committee. It specifically sets forth the makeup of the Board and conforms Kansas Statutes to OBRA 90.

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Section 1 of the bill:

* specifies that the purpose of the DUR program includes prospective as well as retrospective drug utilization;
* specifies that the DUR Board provide educational information to improve prescribing and dispensing practices; and
* deletes a paragraph made unnecessary by the passage of OBRA 90.

Section 2 of SB 410 provides for the membership, appointment, powers and duties of the DUR Board. The seven members of the Board would consist of:

* two licensed and practicing physicians, nominated by the state medical society and appointed by the Secretary of SRS from a list of four nominees;
* one licensed and practicing osteopath, nominated by the state association of osteopathic medicine and appointed by the Secretary from a list of four nominees;
* two licensed and practicing pharmacists, nominated by the state pharmacy association and appointed by the Secretary from a list of four nominees;
* one licensed pharmacist actively employed in academic pharmacy, appointed by the Secretary from a list of two nominees provided by the University of Kansas; and
* one person representing Medicaid consumers appointed by the Governor.

Finally, SB 410 creates an additional exception to the Kansas open meeting law so that the DUR Board would not be subject to that law when considering patient profile information

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or matters relating to identifiable providers. Obviously we have felt all along that when they are considering general policy matters that they would be subject to the open meeting act. SB 410 does not restrict either the DUR Board nor SRS from making recommendations or decisions on drug therapy. Rather, SB 410 serves to facilitate, according to Federal Rules and Regs §456.703:

> The goal of the state's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

We would urge your support of SB 410.

We appreciate this opportunity to offer this testimony, and we would be pleased to attempt to respond to any questions.

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KANSAS DEPARTMENT OF SOCIAL AND REHABILITATION SERVICES
Donna L. Whiteman, Secretary

House Public Health and Welfare Committee
Testimony on Senate Bill 410
March 31, 1993

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SRS Mission Statement

"The Kansas Department of Social and Rehabilitation Services empowers individuals and families to achieve and sustain independence and to participate in the rights, responsibilities and benefits of full citizenship by creating conditions and opportunities for change, by advocating for human dignity and worth, and by providing care, safety and support in collaboration with others."

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Madam Chairman and members of the committee, on behalf of Donna L. Whiteman, I thank you for the opportunity to speak in opposition to Senate Bill 410.

The Kansas Department of Social and Rehabilitation Services opposes the passage of SB 410 because it duplicates, and inappropriately adds requirements to the federal statute known as the Omnibus Budget Reconciliation Act (OBRA) of 1990 that governs the Kansas Drug Utilization Review Program.

OBRA 90 requires that a Drug Utilization Review (DUR) system incorporating both retrospective DUR (with historical paid claims data) and prospective DUR.

Prospective DUR is conducted at the point of sale, and the pharmacist is predominantly responsible for providing this service based on state-approved criteria before the medication is dispensed. The pharmacist conducts a therapeutic screen including drug interactions, duplicative therapy, and drug-disease contraindications.

For the retrospective review requirements, the Kansas Medicaid Program has contracted with the Kansas Pharmacy Foundation since 1976 to provide a Drug Utilization Review Committee. This is a clinical committee which discusses sensitive, confidential, and volatile issues surrounding prescription drug coverage, prescribing, dispensing, and usage. The committee meetings are intended to make unbiased and objective medical and pharmaceutical recommendations to the Division of Medical Services. Over the years, this committee has provided both an objectively managed drug formulary, and reviews of prescribing, dispensing and usage habits, based on medical and pharmaceutical expertise, free of marketing and advertising influence. The prescribed drugs category of SRS Medicaid budget grew 103% between Fiscal Years 1988 and 1992 ($22.7 million to $46.1 million). Inappropriate influences by pharmaceutical sales and marketing personnel on the SRS Medicaid decision-making process would undoubtedly increase costs even further.

The federal statute requires that the committee be composed of licensed physicians (33 1/3% to 51%) and licensed pharmacists (at least 33 1/3%). The DUR process must be under the control of the state Medicaid Program; however, it may be contracted out. The committee, or "Board" to use the federal term, is a

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working group of professional drug usage evaluators who have the knowledge and expertise to research the pertinent literatures, and/or to request personal presentations, as needed.

There is no federal requirement that the public or the pharmaceutical industry be included in the process, nor that any portion of the meetings be open to the public. There is the perception that the drug utilization review process is shielded from public scrutiny by the operations of the nine-member Drug Utilization Review Committee. Governmental secrecy and closed-door decision-making is deeply offensive to Kansans including those in state government.

The work of the DUR Committee represents a very narrow part of the SRS drug utilization review process. Problems, issues and requests for information are assigned to the DUR Committee by the SRS Division of Medical Services. Information and recommendations from the DUR Committee are then incorporated into the decision-making processes of SRS. If the decision involves a change in rules and regulations, the process always involves the monthly open meeting with specific opportunities for public comment and interaction with decision makers. Management staff of the Division of Medical Services meet quarterly with the pharmaceutical industry to discuss issues. The management staff of SRS is open to contact by the general public, including representatives of the pharmaceutical industry, at any time. There are ample opportunities for all concerned - health care providers, Medicaid patients, and representatives of the pharmaceutical industry - to actively participate in the decision-making processes of this agency.

The essential feature of the drug utilization review process is that SRS Medicaid officials, not the DUR Committee, are the decision makers on all pharmaceutical issues. These officials which include the Secretary, Commissioner, Medicaid Director, staff pharmacist and the SRS Policy Committee rely on information from various sources for decision-making purposes. It is essential that one of these sources, the DUR Committee, be free from sales and marketing bias so that objective pharmaceutical recommendations and decisions can be made.

Please vote no on this bill if you want to keep the SRS Medicaid pharmacy costs increasing yet higher from $58.3 million in 1993 and $70.8 million estimated for fiscal year 1994.

Robert L. Epps
Commissioner
Income Support/Medical Services

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Attm #3
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THE KANSAS PHARMACISTS ASSOCIATION
1308 SW 10TH STREET
TOPEKA, KANSAS 66604
PHONE (913) 232-0439
FAX (913) 232-3764

ROBERT R. (BOB) WILLIAMS, M.S., C.A.E.
EXECUTIVE DIRECTOR

TESTIMONY

Senate Bill 410

House Public Health & Welfare Committee

Wednesday, March 31, 1993

My name is Bob Williams. I am the Executive Director of the Kansas Pharmacists Association. Thank you for this opportunity to address the committee regarding Senate Bill 410.

Senate Bill 410 establishes a Medicaid Drug Utilization Review Board. The state of Kansas has had a Medicaid Drug Utilization Review Board for the past fifteen years. As a matter of fact, the state of Kansas was the first state to establish such a program. As a result of the so-called "OBRA 90" legislation passed by Congress, all state Medicaid programs are now required to have Drug Utilization Review programs. The current DUR committee is more extensive than the recommendation of SB-410 in that there are nine members. The DUR committee consists of two physicians, one osteopath, one pharmaceutical chemist, one pharmacologist, three practicing pharmacists, and one registered nurse. The DUR committee is charged with the responsibility of monitoring all clinically-appropriate prescribing/dispensing of covered outpatient drugs, as well as drug use review, evaluation and intervention. The DUR director files an annual report with SRS and publishes 8 newsletters a year which are sent to all prescribers and dispensers in the state.

If the state of Kansas did not currently have a Drug Utilization Review program, the Kansas Pharmacists Association would understand the need for SB-410. However, because the state of Kansas has an established Drug Utilization Review program we find SB-410 to be unnecessary and, therefore, do not recommend its passage.

Thank you.

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drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

"(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:

"(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

"(aa) The name and description of the medication.

"(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

"(cc) Special directions and precautions for preparation, administration and use by the patient.

"(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

"(ee) Techniques for self-monitoring drug therapy.

"(ff) Proper storage.

"(gg) Prescription refill information.

"(hh) Action to be taken in the event of a missed dose.

"(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

"(aa) Name, address, telephone number, date of birth (or age) and gender.

"(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

"(cc) Pharmacist comments relevant to the individuals drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation.

"(B) RETROSPECTIVE DRUG USE REVIEW.—The progra. shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

"(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

"(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

"(3) STATE DRUG USE REVIEW BOARD.—

"(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the 'DUR Board') either directly or through a contract with a private organization.

"(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

"(i) The clinically appropriate prescribing of covered outpatient drugs.

"(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

"(iii) Drug use review, evaluation, and intervention.

"(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ * * * licensed and actively practicing pharmacists.

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"(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

"(i) Retrospective DUR as defined in section (2)(B).

"(ii) Application of standards as defined in section (2)(C).

"(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

"(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

"(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

"(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

"(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

"(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

"(h) ELECTRONIC CLAIMS MANAGEMENT.—

"(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing online, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

"(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

"(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

"(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

"(i) ANNUAL REPORT.—

"(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

"(2) DETAILS.—Each report shall include information on—

"(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

"(B) the total value of rebates received and number of manufacturers providing such rebates;

"(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

"(D) the effect of inflation on the value of rebates required under this section;

"(E) trends in prices paid under this title for covered outpatient drugs; and

"(F) Federal and State administrative costs associated with compliance with the provisions of this title.

"(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—(1) Covered outpatient drugs dispensed by *** Health Maintenance Organizations, including those organizations that contract under section 1903(m), are not subject to the requirements of this section.

"(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

"(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions

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described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

"(k) DEFINITIONS.—In this section—

"(1) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

"(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term 'covered outpatient drug' means—

"(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

"(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

"(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

"(B) a biological product, other than a vaccine which—

"(i) may only be dispensed upon prescription,

"(ii) is licensed under section 351 of the Public Health Service Act, and

"(iii) is produced at an establishment licensed under such section to produce such product; and

"(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

"(3) LIMITING DEFINITION.—The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

"(A) Inpatient hospital services.

"(B) Hospice services.

"(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

"(D) Physicians' services.

"(E) Outpatient hospital services * * * *emergency room visits.

"(F) Nursing facility sevices.

"(G) Other laboratory and x-ray services.

"(H) Renal dialysis.

Such term also does not include any such drug or product which is used for a medical indication which is not a medically accepted indication.

"(4) NONPRESCRIPTION DRUGS.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as 'over-the-counter' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

"(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in—

"(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

"(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"(6) MEDICALLY ACCEPTED INDICATION.—The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, which appears in peer-reviewed medical literature or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

"(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

"(A) DEFINED.—

"(i) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' means, with respect to a calendar quarter, a covered outpatient drug (not including any drug de-

scribed in paragraph (5)) for which there are 2 or more drug products which—

"(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

"(III) are sold or marketed in the State during the period.

"(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term 'innovator multiple source drug' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

"(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term 'noninnovator multiple source drug' means a multiple source drug that is not an innovator multiple source drug.

"(iv) SINGLE SOURCE DRUG.—The term 'single source drug' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers operating under the new drug application.

"(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

"(C) DEFINITIONS.—For purposes of this paragraph—

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

"(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

"(8) STATE AGENCY.—The term 'State agency' means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.".

(b) FUNDING.—

(1) DRUG USE REVIEW PROGRAMS.—Section 1903(a)(3) (42 U.S.C. 1936b(a)(3)) is amended—

(A) by striking "plus" at the end of subparagraph (C) and inserting "and", and

(B) by adding at the end the following new subparagraph:

"(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g); plus".

(2) TEMPORARY INCREASE IN FEDERAL MATCH FOR ADMINISTRATIVE COSTS.—The per centum to be applied under section 1903(a)(7) of the Social Security Act for amounts expended during calendar quarters in fiscal year 1991 which are attributable to administrative activities necessary to carry out section 1927 (other than subsection (g)) of such Act shall be 75 percent, rather than 50 percent; after fiscal year 1991, the match shall revert back to 50 percent.

(c) DEMONSTRATION PROJECTS.—

(1) PROSPECTIVE DRUG UTILIZATION REVIEW.—

(A) The Secretary of Health and Human Services shall provide, through competitive procurement by not later than January 1, 1992, for the establishment of at least 10 statewide demonstration projects to evaluate the efficiency and cost-effectiveness of prospective drug utilization review (as a component of on-line, real-time electronic point-of-sales claims management) in fulfilling patient counseling and in reducing costs for prescription drugs.

(B) Each of such projects shall establish a central electronic repository for capturing, storing, and updating prospective drug utilization review data and for providing access to such data by participating pharmacists (and other authorized participants).

(C) Under each project, the pharmacist or other authorized participant shall assess the active drug regimens of recipients in terms of duplicate drug therapy, therapeutic overlap, allergy and cross-sensitivity reactions, drug interactions, age precautions, drug regiment compliance, prescribing limits, and other appropriate elements.

(D) Not later than January 1, 1994, the Secretary shall submit to Congress a report on the demonstration projects conducted under this paragraph.

(2) DEMONSTRATION PROJECT ON COST-EFFECTIVENESS OF REIMBURSEMENT FOR PHARMACISTS' COGNITIVE SERVICES.—

(A) The Secretary of Health and Human Services shall conduct a demonstration project to evaluate the impact on quality of care and cost-effectiveness of paying pharmacists under title XIX of the Social Security Act, whether or not a drug is dispensed, for drug use review services. For this purpose, the Secretary shall provide for no fewer than 5 dem-

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onstration sites in different States and the participation of a significant number of pharmacists.

(B) Not later than January 1, 1995, the Secretary shall submit a report to the Congress on the results of the demonstration project conducted under subparagraph (A).

(d) STUDIES.—

(1) STUDY OF DRUG PURCHASING AND BILLING ACTIVITIES OF VARIOUS HEALTH CARE SYSTEMS.—

(A) The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the medicaid program. The study shall compare the ingredient costs of drugs for medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies.

(B) The study conducted under this subsection shall include an assessment of—

(i) the prices paid by these institutions for covered outpatient drugs compared to prices that would be paid under this section,

(ii) the quality of outpatient drug use review provided by these institutions as compared to drug use review required under this section, and

(iii) the efficiency of mechanisms used by these institutions for billing and receiving payment for covered outpatient drugs dispensed under this title.

(C) By not later than May 1, 1991, the Comptroller General shall report to the Secretary of Health and Human Services (hereafter in this section referred to as the "Secretary"), the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the study conducted under subparagraph (A).

(2) REPORT ON DRUG PRICING.—By not later than May 1 of each year, the Comptroller General shall submit to the Secretary, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and House of Representatives an annual report on changes in prices charged by manufacturers for prescription drugs to the Department of Veterans Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

(3) STUDY ON PRIOR APPROVAL PROCEDURES.—

(A) The Secretary, acting in consultation with the Comptroller General, shall study prior approval procedures utilized by State medical assistance programs conducted under title XIX of the Social Security Act, including—

(i) the appeals provisions under such programs; and

(ii) the effects of such procedures on beneficiary and provider access to medications covered under such programs.

(B) By not later than December 31, 1991, the Secretary and the Comptroller General shall report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the results of the study conducted under subparagraph (A) and shall make recommendations with respect to which procedures are appropriate or inappropriate to be utilized by State plans for medical assistance.

(4) STUDY ON REIMBURSEMENT RATES TO PHARMACISTS.—

(A) The Secretary shall conduct a study on (i) the adequacy of current reimbursement rates to pharmacists under each State medical assistance programs conducted under title XIX of the Social Security Act; and (ii) the extent to which reimbursement rates under such programs have an effect on beneficiary access to medications covered and pharmacy services under such programs.

(B) By not later than December 31, 1991, the Secretary shall report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the results of the study conducted under subparagraph (A).

(5) STUDY OF PAYMENTS FOR VACCINES.—The Secretary of Health and Human Services shall undertake a study of the relationship between State medical assistance plans and Federal and State acquisition and reimbursement policies for vaccines and the accessibility of vaccinations and immunization to children provided under this title. The Secretary shall report to the Congress on the Study not later than one year after the date of the enactment of this Act.

(6) STUDY ON APPLICATION OF DISCOUNTING OF DRUGS UNDER MEDICARE.—The Comptroller General shall conduct a study examining methods to encourage providers of items and services under title XVIII of the Social Security Act to negotiate discounts with suppliers of prescription drugs to such providers. The Comptroller General shall submit to Congress a report on such study no later than 1 year after the date of enactment of this subsection.

Drug Utilization Review Committee 1992 Annual Report

One of the biggest changes in calendar year 1992 was the State's request for a proposal (RFP) for a DUR data sorter. Four bids were received, and First Health Services Corporation of Glen Allen, Virginia, was awarded the contract. First Health receives monthly claims information from Electronic Data Systems (EDS). The information is then run through a complex computer program to provide the DUR Committee with patient profiles that have potential problems. The Committee then reviews these profiles to determine if a letter should be sent to providers. In June the committee began to receive profiles from First Health; below are charts summarizing the activity for 1992.

Number of profiles received:

June - 599 profiles (2,800+ pages)
July - 200 profiles (752 pages)
August - 239 profiles (882 pages)
September - 342 profiles (1,439 pages)
October - 480 profiles (1,741 pages)
November - 419 profiles (1,142 pages)
December - 626 profiles (2,219 pages)

Number profiles warranting letters:	**Number of letters sent:**	**Responses received:**
June - 53	June - 66	34
July - 21	July - 25	12
August - 26	August - 27	17
September - 105	September - 126	80
October - 63	October 85	56
November - 37	November - 94	28 as of 1/26/93
December - 96	December 108	52 as of 1/26/93

Prior authorization criteria. During the year, the DUR Committee reviewed the prior authorization criteria for several products. The following is a summary of products reviewed and the committee's recommendations:

Hemophilia products - PA be discontinued
Growth hormone - recommended changes
Rifampin (Rifadin, MMD)- approved changes recommended by the EDS Drug Review Unit
Amiodarone (Cordarone, Wyeth Ayerst) - recommended changes
Cyclosporine (Sandimmune, Sandoz) - recommended prior authorization be removed

New Drug Evaluations. The following products were reviewed by the Committee with the following recommendations:

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New Drug Evaluations. The following products were reviewed by the Committee with the following recommendations:

Nicotine patches - committee recommended that these products not be added to the formulary due to the high cost of the products and low success rate

Anistreplase (eminase, SKB) - recommended it be added to the physician's injection list

Procuren - recommended this be a non-covered product

DTAP - recommended this product be added to the physician's injection list

Carnation nutren - recommended this product be covered under Durable Medical Equipment

Various wound care products - recommended these products be covered under Durable Medical Equipment

Benzodiazepine hypnotics - recommended these be non-covered products

Ace Inhibitor Audit. The Committee worked with the Drug Review Unit to perfect the Ace Inhibitor Audit. This audit identified people taking an ACE inhibitor with potassium and no loop diuretic. After receiving profiles for several months, the audit was turned off, since First Health was identifying this drug interaction in their system.

Narcotic Audit. The committee worked with the Drug Review Unit on this audit to identify potential narcotic abusers. Two audits were in place by October 1991. One identified adults receiving multiple narcotic prescriptions. These were forwarded to the Surveillance Utilization Review (SUR) Unit. The other identified children under one year of age receiving narcotics. Over 100 referrals were reviewed in 1992. 69 letters were sent and 26 responses were received. In November the DUR Committee voted to temporarily turn off this audit since the same physicians were being identified and will consider turning on the audit again in the near future.

Referrals from the SURs Unit. The EDS Surveillance Utilization Review (SUR) referred nine cases to the DUR Committee for input. In several instances the DUR Committee sent a letter to the physician regarding some of the findings by the SURs Unit.

Lock-In Letters. In May 1992, the DUR Committee became involved in the lock-in process. After a recipient had been placed on lock-in, the DUR Committee would send letters to providers informing them of their patient's lock-in status. This was done to increase communication and to prevent recipients from obtaining abusable prescriptions from multiple physicians. In October, pharmacy providers were also included. Throughout the year, 314 lock-in letters were mailed and 120 responses were received (26% response rate). Based on the responses, the lock-in letters were appreciated by providers.

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Clozaril Letters. In February 1992, the committee began sending letters to physicians who had prescribed Clozaril for their patients. Throughout the year, more than 100 letters were sent to physicians stating the necessary precautions which needed to be taken. Only two phone calls and one written response have been received. In 1993 the committee will need to evaluate whether these letters should be continued.

Trental Follow-up Study. A follow-up to the 1991 Trental study was completed showing a 33.5% decrease in the number of recipients receiving Trental and a 25.5% decrease in the number of physicians prescribing Trental.

H_2 Follow-Up Study. In 1992 the follow-up to the H_2 study conducted in '91 was completed. The results were as follows: 277 recipients were in the initial study with 267 recipients receiving an H_2 and Carafate/Prilosec and 10 receiving two H_2 antagonists concurrently. In the follow-up of the 267 recipients receiving an H_2 and Carafate/Prilosec, 134 had discontinued the pattern and 107 had continued the pattern. One recipient began taking two H_2s concurrently, and 25 recipients were not able to be followed. Of the 10 recipients in the initial study that were taking two H_2 antagonists concurrently, seven had discontinued the pattern, one continued the pattern, one began taking an H_2 with carafate and one recipient was not able to be followed.

Lincomycin Follow-up Study. In the initial study 80 physicians or physician groups were identified prescribing lincomycin. 40 of the 80 physicians in the initial study continue to bill for lincomycin in the follow-up period. In addition, 43 new physicians or physician groups appeared in the follow-up study that were not in the initial study period. The results of this study signify that lincomycin prescribing continues to be a problem in Kansas, and the DUR Committee will need to continue educating providers on the uses of lincomycin.

NSAIDs follow-up Study. This follow-up study will be completed in 1993.

Educational Programs. In 1992 there were several educational programs on the Kansas DUR program and OBRA 90. Myron Leinwetter, DUR committee member, gave a one-hour presentation at the Kansas Pharmacy Annual Meeting in Lawrence, KS. At seven KPhA district meetings, a brief presentation was given on the DUR program. A handout on OBRA 90 (see attachment) was distributed at all of these programs.

DUR Newsletter. Four issues of the Kansas DUR Newsletter have been sent to providers. Other issues are in the editing process.

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KANSAS DRUG UTILIZATION REVIEW NEWSLETTER
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CONSIDERATIONS IN THE USE OF ANTIPSYCHOTICS

THERAPEUTIC USE

Antipsychotics have become the keystone of treatment of schizophrenic disorders. Delusions, hallucinations, and bizarre behavior may be at least partially controlled by adequate doses of these agents. Nonpsychiatric uses of these agents include prevention of vomiting, control of hiccups, and management of Huntington's chorea and Tourette's syndrome. The prolonged use of these agents may lead to certain undesirable outcomes. Even at moderate dosages, parasympatholytic, or atropinelike effects and Parkinsonism are common. At higher doses, lens opacities, and tardive dyskinesia are potential concerns.

All antipsychotics are equally effective in the treatment of psychoses when they are administered in equipotent doses. For example, chlorpromazine 100 mg is approximately equal to trifuoperazine 4 mg or haloperidol 2 mg.

USAGE IN CHILDREN

Chlorpromazine use in children was first reported in 1953, followed by several studies in childhood disorders beginning in 1955. The indications for antipsychotics in children are limited. Close follow-up and in general short-term management would be suggested. Antipsychotic use in children has focused on the severe disorders of early infantile autism, pervasive development disorder, schizophrenia, and symptoms of aggressive and explosive behavior and affect. Tourette's and other tic disorders are commonly treated with haloperidol.

Some mg/kg/day dosage recommendations include chlorpromazine and thioridazine 2.5, trifluoperazine and thiothixene 0.25, and haloperidol 0.05-0.1 These dosage recommendations may be significantly varied depending on severity of the symptoms, range of response, and age.

EFFICACY COMPARISONS

No single antipsychotic or class of antipsychotics has been demonstrated to be superior in the treatment of schizophrenia. In addition, there is nothing to suggest that any one antipsychotic is more effective for the management of either mania or organic brain syndromes. Therefore, the choice of an antipsychotic is generally not made on the basis of efficacy.

Anecdotally, individual patient may respond better to an agent from one class than to another. However, clinical trials have failed to demonstrate much benefit in switching to another class following nonresponse to an adequate trial of an antipsychotic. Clozapine may be the one exception to this statement.

ADVERSE EFFECTS

Adverse effects are commonly the distinguishing feature among antipsychotics. Adverse effects include anticholinergic effects, sedation, orthostatic hypotension, and acute-onset extrapyramidal side effects. Low-potency agents (See Table 1) are less often associated with extrapyramidal side effects. On the other hand, these agents are more commonly associated with sedation, anticholinergic effects, and hypotension. The incidence of late-onset extrapyramidal side effects is not thought to differ among antipsychotics. Of concern with clozapine is its potential to produce serious hematological side effects.

Extrapyramidal side effects may occur more common in children than in adults. However, anecdotally, dystonic and parkinsonlike reactions may have only a 25% incidence compared to 40-60% with adults. Tardive dyskinesia is thought to occur less commonly in children than adults. As in adults, these reactions are more likely with high potency antipsychotics.

CE OF AGENTS

The choice of an antipsychotic is not based on comparative efficacy. Some of the more commonly used agents include thioridazine, chlorpromazine, fluphenazine, and haloperidol. Thioridazine has the lowest incidence of extrapyramidal side effects. Chlorpromazine, unlike thioridazine, is not associated with dose-d pigmentary retinopathy and therefore serves as a useful low-potency alternative. Both haloperidol and fluphenazine are high potency agents available in long-acting injectable forms. The following points should be considered when prescribing an antipsychotic:

1. All antipsychotics are therapeutically equivalent when used in equipotent doses.

2. A single bedtime dose is preferred. Sustained release formulations are more expensive and offer no advantage.

3. Hyperactivity and agitation may respond in hours; weeks may be required for delusions and hallucinations.

4. Duration of therapy varies widely. Chronic therapy should be reviewed annually for possible discontinuance.

5. Multiple antipsychotics provide no advantage over an optimized single agent.

TABLE 1—ANTIPSYCHOTIC DRUG COMPARISON CHART

DRUG CLASS/DRUG	FORMS^	ORAL DOSAGE EQUIV.
PHENOTHIAZINES		
Chlorpromazine* (Thorazine)	T, L, I, S	100 mg
Fluphenazine* (Permitil, Prolixin)	T, L, I, D	2
Perphenazine* (Trilafon)	T, L, I	8
Thioridazine* (Mellaril)	T, L	100
Trifluoperazine* (Stelazine)	T, L, I	4
THIOXANTHINES		
Thiothixene* (Navane)	T, L, I	3
Chlorprothixene (Taractan)	T, L, I	44
BUTYROPHENONE		
Haloperidol* (Haldol)	T, L, I, D	2
OTHERS		
Loxapine (Daxolin, Loxitane)	T, L, I	10
Molindone (Moban)	T, L	10

* Available generically

^ Dosage forms: T: Tablet/capsule, L: Liquid, I: injection, D: long-acting injection

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Philip J. Schneider, Pharm.D.

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Drug Utilization Review

FOR YOUR INFORMATION (continued...)

Marion Merrell Dow, Inc. has modified the labeling information of terfenadine (Seldane® and Seldane-D®) as follows:

WARNING

QT INTERVAL PROLONGATION/VENTRICULAR ARRHYTHMIA

RARE CASES OF SERIOUS CARDIOVASCULAR ADVERSE EVENTS, INCLUDING DEATH, CARDIAC ARREST, TORSADES DE POINTES, AND OTHER VENTRIBULAR ARRHYTHMIAS, HAVE BEEN OBSERVED IN THE FOLLOWING CLINICAL SETTINGS, FREQUENTLY IN ASSOCIATION WITH INCREASED TERFENADINE LEVELS WHICH LEAD TO ELECTROCARDIOGRAPHIC QT PROLONGATION:

1. CONCOMITANT ADMINISTRATION OF KETOCONAZOLE (NIZORAL)
2. OVERDOSE, INCLUDING SINGLE DOSES AS LOW AS 360 MG
3. CONCOMITANT ADMINISTRATION OF ERYTHROMYCIN
4. SIGNIFICANT HEPATIC DYSFUNCTION

TERFENADINE IS CONTRAINDICATED IN PATIENTS TAKING KETOCONAZOLE OR ERYTHROMYCIN AND IN PATIENTS WITH SIGNIFICANT HEPATIC DYSFUNCTION.

DO NOT EXCEED RECOMMENDED DOSE.

IN SOME CASES, SEVERE ARRHYTHMIAS HAVE BEEN PRECEDED BY EPISODES OF SYNCOPE. SYNCOPE IN PATIENTS RECEIVING TERFENADINE SHOULD LEAD TO DISCONTINUATION OF TREATMENT AND FULL EVALUATION FOR POTENTIAL ARRHYTHMIAS.

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TABLE 2—ANTIPSYCHOTIC USAGE (June 1992 Data)

ANTIPSYCHOTIC	TOTAL PRESCRIPTIONS	TOTAL $ PAID	AVERAGE PAYMENT
Phenothiazines	4,001	$75,410.00	$ 18.85
Thioxanthines	582	11,742.00	20.17
Butyrophenone	1,862	26,332.00	14.14
Clozaril	514	39,898.00	77.62
Others	447	33,209.00	74.29

FOR YOUR INFORMATION

1991 Annual Report: In 1991 over 700 letters were mailed to prescribing physicians by the DUR Committee. These letters were in regard to studies conducted by the DUR Committee in conjunction with the EDS Drug Review Unit. Studies were conducted on Trental, narcotic agonists/combinations, lincomycin, dextro-thyroxine, non-steroidal anti-inflammatory drugs (NSAIDs), H2 antagonists and miscellaneous anti-ulcer agents.

Accurate physician ID numbers: One problem that the DUR committee continually deals with is having inaccurate information on prescribing physicians. **Please remember** to use correct physician ID numbers on pharmacy claims. If a new provider list is needed, request a copy from EDS by mail (see Section 1100 of General Information in your provider manual) or by calling the Provider Assistance line at 1-800-658-4677 (in Topeka 273-5700.)

What's new in 1992: The Kansas Department of Social and Rehabilitation Services (SRS) has signed a contract with First Health Services Corporation in Glen Allen, Virginia to assist the Kansas DUR Committee with retrospective drug utilization review. First Health will receive all claims information from Electronic Data Services (EDS) and provide the DUR Committee with exception profiles identified by the computer through therapeutic exception criteria. The DUR Committee will then review the profiles and determine if letters need to be sent to prescribing physicians and/or dispensing pharmacies. Each month the DUR Committee will focus on specific therapeutic class or classes. In June, the DUR Committee received their first profiles from First Health focusing on systemic antifungals, antihyperlipidemic agents, and non-steroidal anti-inflammatory drugs (NSAIDs).

DRUG USAGE FREQUENCY BY THERAPEUTIC CLASS (June 1992)
(Ranked by Total Amount Paid)

THERAPEUTIC CLASS	TOTAL $ PAID	# OF RX	AVE. PRICE PER RX
H2 antagonists	$324,931.00	5,029	$64.61
Non-steroidal anti-inflammatory agents	233,959.00	7,586	30.84
Calcium channel blockers	232,922.00	4,767	48.86
ACE inhibitors	126,076.00	3,180	39.65
Anti-asthmatics sympathomatics	116,764.00	5,276	22.13
2nd generation cephalosporins	114,332.00	2,740	41.73
Miscellaneous	110,846.00	2,725	40.68
Fluoroquinolones	88,827.00	1,741	51.02
Antipsychotics phenothazines	75,410.00	4,001	18.85
Antidepressants tricyclic agents	74,832.00	4,783	15.65

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DUR EVALUATION COMMITTEE

KANSAS DRUG UTILIZATION REVIEW

PHYSICIAN REPRESENTATIVES:

Raymond S. Freeman, M.D. *
1901 E. Iron
Salina, KS 67401
Home: 913/827-3520

Myron Leinwetter, D.O. *
Rossville Clinic
423 Main
Rossville, KS 66533
Home: 913/584-6597
Work: 913/584-6705

PHARMACOLOGIST REPRESENTATIVE:

Ruben Bunag, M.D. *
10301 Barton
Overland Park, KS 66214
Work: 913/588-7507
Home: 913/588-7140

PHARMACEUTICAL CHEMIST:

Kenneth L. Audus *
Dept. of Pharmaceutical Chemistry
School of Pharmacy, Malott Hall
The University of Kansas
Lawrence, KS 66045
Work: 913/864-3609

PHARMACIST REPRESENTATIVES:

John Lowdermilk *
1112 No. 14
Marysville, KS 66508
Work: 913/562-3196
Home: 913/562-5415

Kathy Miller-Lemke, R.Ph. *
Holst Pharmacy
611 Holiday Plaza
Lansing, KS 66043
Work: 913/727-3300
Home: 913/727-2370

STATE MEDICAID REPRESENTATIVES:

Gene Stephens, R.Ph.
Pharmacy Services Director
Medical Programs Division
Docking Bldg., 6th Floor
Topeka, KS 66612
Work: 913/296-3981
Home: 913/266-0457

Joanie Lewerenz
Medical Programs Division
Docking Bldg., 6th Floor
Topeka, KS 66612
Work: 913/296-3981

NURSE REPRESENTATIVE:

Barbara Walker, R.N. *
12020 Gardner Rd.
Olathe, KS 66061
Work: 913/782-1372

KANSAS PHARMACY FOUNDATION REPRESENTATIVE:

Roger Miller, R.Ph. *
Miller's Pharmacy
Box 417
Bonner Springs, KS 66012
Work: 1-800-333-8097
Home: 913/422-5191

CONSULTANTS

Jim Pessetto, R.Ph.
5821 Mullen
Shawnee, KS 66216
Work: 913/588-2330
Home: 913/286-7392

Greg Lee, R.Ph.
Super D Drug
500 W. 10th
Topeka, KS 66612
Work: 913/235-6289
Home: 913/266-4187

ACTING DUR PROGRAM DIRECTOR

Larry Tremel
16209 W. 81st Terr.
Lenexa, KS 66219
Work: 913/588-2373
Home: 913/599-1939

* Voting members

PH+C6.

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ARTHRITIS FOUNDATION®

KANSAS CHAPTER

1602 E. WATERMAN
WICHITA, KANSAS 67211
316/263-0116
1-800/362-1108

March 30,. 1993

Joann Flower
State Representative
Capitol
Topeka, KS 66612

Dear Ms. Flower:

I am writing on behalf of the Arthritis Foundation, Kansas Chapter, in support of 1993 Senate Bill 410.

Access to modern and effective medication for treatment of arthritis and other serious diseases is an important matter for private pay and medicaid-supported patients alike. Access to such medication for medicaid recipients, however, is controlled entirely by the state welfare agency, SRS. As a result, decisions by the agency which deny access or payment for certain medications need to be made in full public view and not behind closed doors.

I remember well when SRS eliminated all effective arthritis medicine from the medicaid formulary. When the news became public, Kansans were outraged. Complaints flowed ino then Governor Hayden, and he overturned the decision on arthritis medication and other medicines. Frankly, if the decisions had been made by a board of qualified professionals in an open setting, all this fuss would have been avoided.

S-410 would prevent further mishaps like the 1989 formulary restrictions that frustrated and angered our members. I urge you to support S-410.

Thank you for your consideration. Many people will be greatly affected by this bill.

Sincerely,

Doris E. Newman

Doris E. Newman, President
Arthritis Foundation, Kansas Chapter

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