Approved: 3-31-93
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by Chair Sandy Praeger at 10:00 a.m. on March 16, 1993 in Room 526-S of the Capitol.

All members were present except:

Committee staff present: Norman Furse, Revisor of Statutes
William Wolff, Legislative Research Department
Emalene Correll, Legislative Research Department
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

William C. Rein, Director, Hospital and Medical Programs, Kansas Department of Health and Environment
Robert T. Gibbons, MD, Medical Director, Surgicenter of Johnson County
Margaret Orman, Regional Director, Medical Care International, partner - Surgicenter of Johnson County/Wichita
Carolyn Exley, Administrator of Surgicare of Wichita
Marvin M. Fairbank, Executive Director, Topeka Single Day Surgery
Harold Riehm, Executive Director, Kansas Association of Osteopathic Medicine
Margot Gendreau Lenzi, Chair of the Pharmaceutical Manufacturers Association Task Force in Kansas
Bob Williams, Executive Director, Kansas Pharmacists Association
Robert L. Epps, Commissioner, Income Support/Medical Services, SRS
Larry Tremel, Assistant Director of Pharmacy, KUMC

Others attending: See attached list

Hearing on **SB 402** - Ambulatory surgical center defined.

William C. Rein, KDHE, appeared in support of **SB 402** in which the bill would amend the licensing statute for ambulatory surgical centers at KSA 65-425(f). Two changes would be made if the bill passed: (1) allow patients to remain in an ambulatory surgical center overnight but not to exceed 24 hours, and (2) allow physicians to leave the surgical center when patients have "recovered from the obvious effects of anesthetic." Mr. Rein suggested clarification of the language should be made on page 1, line 38, referring to physicians being allowed to leave the facility prior to full anesthesia recovery in order to comply with medicare regulations. (Attachment 1) In answer to a question, Mr. Rein stated the bill would allow an ambulatory surgical center to be opened 24 hours a day, and thus may compete with licensed hospitals. Most states do have a 24 hour provision -- some 48-72 hours.

Dr. Robert T. Gibbons, Surgicenter of Johnson County, appeared in support of **SB 402** and gave a brief history of freestanding ASC's in the U.S. and Kansas, current status of ambulatory surgical technology and capabilities, problems with the current law, and proposed solutions to those problems. (Attachment 2)

Margaret Orman, Medical Care International, presented her support for **SB 402** and stated her organization, which is composed of ninety-one surgery centers in twenty-five states, provides free or very low cost services to unemployed, uninsured and indigent persons, as well as medicare and medicaid patients. Ms. Orman also noted that patients in Oklahoma, Texas and Missouri are allowed to stay in surgical center facilities up to 24 hours. (Attachment 3) In answer to a member's question, Ms. Orman stated the patients would be charged extra if they stayed past midnight.

Carolyn Exley, Surgicare of Wichita, appeared in support of the proposed bill, (Attachment 4) as well as Marvin Fairbank, Topeka Single Day Surgery. (Attachment 5)

During Committee discussion, Dr. Gibbons addressed the issue regarding charges by surgical centers made to the patient for the procedure, which is a flat charge, rather than by the day. The only increase charge for an overnight stay would be relative to that portion of care, usually in the range of $150 to $300 which would cover an extended recovery stage, which is not included in the base rate of the procedure. There would be no conflict if

hours are extended in regard to medicare or medicaid patients. Dr. Gibbons stated he is in agreement with the recommendation by Mr. Rein that language be changed on page 1, line 38, of the bill regarding compliance with medicare regulations. The revisor will draft a balloon of the bill showing the proposed amendment.

There were no opponents testifying on **SB 402**.

Hearing on **SB 410** - Creating a medicaid drug utilization review board.

Harold Riehm, KAOM, expressed support for **SB 410** and in particular New Sec. 2(b)(f) which is a "sunshine" provision to require that meetings of the board be open meetings in which interested parties may observe the deliberation process. (Attachment 6)

Also speaking in support of **SB 410** was Margot Gendreau Lenzi, Chair of the Pharmaceutical Manufacturers Association Task Force in Kansas, who outlined the specifics of the bill. She noted that the bill does not restrict the DUR board nor SRS from making recommendations or decisions on drug therapy, but rather the bill serves to facilitate, according to federal rules and regulations, "that the goal of the state DUR program is to assume appropriate drug therapy while permitting sufficient professional prerogatives to allow for individualized drug therapy." Attachment 7)

Bob Williams, Kansas Pharmacists Association, appeared in opposition to **SB 410** stating that Kansas currently has an established drug utilization review program and sees no need for the bill. He stated that the current DUR committee is more extensive than the recommendations of **SB 410** in that there are nine members, and they are charged with the responsibility of monitoring all clinically-appropriate prescribing/dispensing of covered outpatient drugs, as well as drug use review, evaluation and intervention. (Attachment 8)

Robert L. Epps, SRS, expressed his opposition to **SB 410** stating the bill 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. Currently, the DUR committee is not covered by the Kansas Open Meeting Act, as it is not a state agency or committee, but is a group of professionals who serve SRS under a contract between SRS and a private foundation, the Kansas Pharmacy Foundation. He noted that the bill is unnecessary under federal statutes and would allow pharmaceutical sales and marketing personnel to exert inappropriate influence on the Drug Utilization Review process. (Attachment 9)

Larry Tremel, KUMC Pharmacy, appeared in opposition to **SB 410** and stated since there is currently a functional DUR committee in Kansas, there is no need for the bill, and feels the pharmaceutical manufacturers could in some way bias or influence decision making. Committee discussion related to members of the DUR board being able to make decisions without pharmaceutical manufacturers promoting their drugs, and the advantages to the public for having "open meetings." The Chair stated that clarification should be obtained regarding whether SRS, even though they contract, would be absolved from the "Open Meetings Act."

Written testimony in support of the bill was submitted by Doris E. Newman, President, Arthritis Foundation, Kansas Chapter. (Attachment 10)

The meeting was adjourned at 11:00 A.M.

The next meeting is scheduled for March 17, 1993.

GUEST LIST

COMMITTEE: SENATE PUBLIC HEALTH AND WELFARE DATE: 3-16-93

NAME	ADDRESS	COMPANY/ORGANIZATION
CAROL A. CURTIS	K.C. Mo	Zeneca Pharmaceuticals
Bill Rein	Topeka	KDHE
Gene Stephens	Topeka	SKS/DMS
Margaret Orman	Wichita	Medical Laboratories
Carolyn Exley	Wichita	Surgicare of
[illegible] Loges	Overland Park KS	Surgeries
MARVIN FAIRBANK	Topeka	[illegible]
Robert Epps	Topeka	SRS
Mindy Lester	Topeka	PhRMA
Marcia Keyi	Columbus Ohio	Boehringer Ingelheim
Frank Pesci	Washington D.C.	PhRMA
Bill Howell	Kansas City KS	UPJOHN CO.
Tom Whitaker	Topeka	[illegible]
Brad Smoot	Topeka	Pfizer, Inc.
John Peterson	Topeka	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]

State of Kansas
Joan Finney, *Governor*

Department of Health and Environment
Robert C. Harder, Secretary Reply to:

TESTIMONY PRESENTED TO

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

BY

THE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

Senate Bill 402

Introduction

Senate Bill 402 would amend the licensing statute for ambulatory surgical centers at KSA 65-425(f). If passed, this bill would make two changes, neither of which would substantially affect current licensure regulations. Those changes would: (1) allow patients to remain in an ambulatory surgical center overnight but not to exceed 24 hours, and (2) allow physicians to leave the surgical center when patients have "recovered from the obvious effects of anesthetic."

Background

In recent years, some owners of ambulatory surgical centers, and physicians staffing those centers, have argued that patients should be allowed to remain in the facility overnight. This would allow centers to schedule surgery later in the day and still assure that patients would not be discharged before they were ready. However, since the original concept of ambulatory surgery was something which could be completed without an overnight stay, surgical centers have been required to dismiss patients before midnight on the day of surgery. This interpretation was based on provisions of the current licensing statute which prohibits facilities from providing "services or accommodations [for the patient] to stay **overnight**."

The amendment which would authorize physicians to leave the facility after patients had recovered from the obvious effects of anesthesia would still require that physicians be "available" whenever a patient is in the facility. Moreover, the law would continue to provide for registered professional nursing services whenever a patient is in the facility. Nonetheless, it should be noted that Medicare regulations, 42 CFR 416.42 (a), require each patient to be evaluated by a physician for proper anestheisa recovery "before discharge." As currently worded, the proposed amendment beginning on page one, at line 38, might allow physicians to leave the facility prior to full anesthesia recovery.

Senate PH&W
Attachment #1
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Issues

The desire of center owners and staff physicians to provide surgery later in the day, thus necessitating that facilities remain open during evening and nighttime hours, may change the original concept of "same day" surgery. However, the ability to provide more surgical procedures in an ambulatory setting may reduce health care costs.

Recommendations

The Kansas Department of Health and Environment (KDHE) recognizes that changing technology and expanded hours may provide greater options for patients to obtain surgical services in an ambulatory setting. For that reason, KDHE supports passage of Senate Bill 402.

Thank you for the opportunity to present testimony. I would be happy to answer any questions you may have.

Presented by: William C. Rein, Director, Hospital and Medical Programs
Bureau of Adult and Child Care
Kansas Department of Health and Environment
March 16, 1993

STATE OF KANSAS
SENATE HEALTH AND WELFARE COMMITTEE HEARING
MARCH 16, 1988
SENATE BILL 402

Comments submitted in outline form for the sake of brevity by Robert T Gibbons MD, Medical Director, Surgicenter of Johnson County

I. Introductory remarks

II. Brief history of freestanding ASC's in US and Kansas
- first ASC started in Phoenix, AR in 1969 by Drs. Wally Reed and John Ford
- first ASC in KS started in Wichita by Dr. Bob Knapp in 1974
- Dr. Knapp helped write the current law
- now over 1000 freestanding ASCs in the USA

III. Brief history of KSA 65-425
- written nearly twenty years ago to conform with then current knowledge
- essentially unchanged since that time
- limited to **NO** overnight stay

IV. Current status of ambulatory surgical technology and capabilities
- anesthesia and surgical capabilities have greatly improved in last twenty years
- procedures which required days of hospitalization in 1974 are routinely being accomplished as an outpatient today
- a small number of patients (about two or three per thousand) require hospitalization for observation, pain control, or basic nursing care.
- emergency transfer to the hospital is extremely rare because ASC will stabilize patients before transfer

V. Problems with the current law
- is arbitrary in that it descriminates against patients operated upon late in the day
- forces patients into an eleventh hour transfer when nursing staff levels at the hospital are at their lowest
- disrupts continuity of care for patient
- can cost $1500 dollars extra or more for the cost of ambulance plus hospitalization

VI. Solution to the Problem
- allow freestanding ASC to keep patients over night as hospital based ASC s can
- patients will have continuity of care, both nursing and medical
- patients will have a higher level of nursing intensity than in the hospital
- patients will save money
- no sacrifice in quality of care
- the rare seriously ill patients needing intensive care or more invasive surgical procedure will still be transferred as before

Senate PH&W
attachment #2
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My name is Margaret Orman. I am a Regional Director for Medical Care International which is the General Partner and Managing Partner at Surgicare of Wichita and Surgicenter of Johnson County. Our company has ninety one surgery centers in twenty five states. Thirty of these facilities currently have the capability of offering their patients post-operative observation for at least twenty four hours. Over 2500 patients were cared for in this manner in 1992 and there were no serious complications.

I would like to ask you to support Senate Bill 402. This bill would allow Ambulatory Surgery Centers in Kansas to keep patients in the center for observation for up to twenty four hours. Currently, we may not keep patients past midnight. By allowing ASCs to keep patients for up to twenty four hours, we would be able to provide better continuity of care for our patients for pain management, additional monitoring or observation, replacement of fluids with infusion therapy, and administration of intravenous medications.

I personally have been involved with ambulatory surgical centers since 1974 when the first ASC in Kansas (in Wichita) was licensed. I have seen that ASCs provide high quality patient care. In the State of Kansas, ASCs must meet strict State regulations as well as Medicare regulations. The Surgicenter of Johnson County is accredited by the Accreditation Association of Ambulatory Health Care (AAA/HC) and Surgicare of Wichita has been accredited with

Senate PH&W
Attachment # 3
3-16-93

commendation by the Joint Commission for Accreditation of Health Care Organizations (JCAHO). Each of these accrediting bodies sets high standards for quality of care and many ASCs voluntarily seek accreditation.

Ambulatory surgical centers are also cost effective. Recent data released by Blue Cross/Blue Shield of North Carolina and Florida show that freestanding ASCs are far less expensive than hospital-based outpatient facilities. In North Carolina charges were 44% lower in freestanding ASCs and in Florida charges were 25% lower in freestanding ASCs.

Ambulatory surgical centers care for Medicare patients and Medicaid patients. We also provide free or very low cost services to unemployed, uninsured or indigent persons.

The original ASC rules were adopted almost twenty years ago. Perhaps at that time a restrictive length of stay might have been appropriate; there was no history - the surgery center in Wichita was not only the first in the state but also among the first ten to open in the United States. We now have a track record of quality and safety. Given the advances in technology and anesthesia care, we feel that it is essential that our patients and the residents of the State of Kansas be afforded the continuity of care that observation in an ASC for up to twenty four hours will provide.

My name is Carolyn Exley and I am from Wichita, Kansas. I am the administrator of Surgicare of Wichita and I wish to offer comment in support of the currently proposed bill change that would allow ASCS in Kansas to provide care to their patients for up to 24 hours.

The regulations governing ASCS were developed in the 1970s when surgical technology was not as complex as it is in the 1990s. The patients in this new era of innovative surgical technology aren't sicker and do not need to be in the hospital but do require individualized care with all their needs met regarding pain control, safety, nutrition, convenience and cost considerations. Also with the capability of keeping patients overnight the surgeons would be able to work at the ASC facility with a greater level of comfort knowing they have the capability of caring for their patients for an extended period of time should such a stay be warranted.

I truly hope that much consideration will be given to adopting Senate Bill 402 to allow patients to be kept in the ASC facility for up to 24 hours. This could provide one of the answers to the growing need for high quality, cost effective health care in the state of Kansas.

Senate P H & W
Attachment 4
3-16-93

KANSAS SENATE; COMMITTEE ON HEALTH AND WELFARE

TESTIMONY RE: S.B. 402

MARCH 16, 1993

MARVIN M. FAIRBANK, TOPEKA

My name is Marvin Fairbank. I am a resident of rural Topeka, Kansas, and the executive director of Topeka Single Day Surgery a licensed ambulatory surgery center in Topeka, Kansas.

My purpose for speaking to you today is to support the passage of S.B.402. The bill, if passed will amend the present language of KSA 65-425, the licensing law covering Ambulatory Surgery Centers (ASC's) to allow patients to be kept up to 24 hours.

While the ASC licensing law has served the public of the State reasonably well over the past twenty years, the delivery of ambulatory surgery has changed radically in that period. Procedures that only a few years ago required hospital stays of up to a week, are now done in freestanding ambulatory surgery centers, where the patients are safely sent home the evening of the procedure. When the law was written no one anticipated the widespread use of televideoscopic surgery that would revolutionize orthopedics, gynecology, and most recently general surgery. Developments in the field of anesthesia have also contributed greatly to the growth of the out patient surgery concept. In today's ASC, complicated procedures like laparoscopic cholecystectomy, endometrial ablation, and anterior cruciate ligament repair are successfully carried out on a regular basis. Though the need for overnight stays after these procedures is fairly rare (less than .5% in 1992 in Topeka ASC), it occasionally happens that patients' conditions require observation overnight. Rather than experience an expensive transfer and overnight admission, patients would be better served if ASC's were allowed to care for them on site.

The State of Kansas and Medicare inspect these facilities annually. The requirements for ASC's are at least as stringent as those for hospital operating services. At present hospitals may monitor outpatients overnight without "admitting" them. There is no reason to believe that ASC's would offer less safety for the patients requiring post operative observation overnight than they receive in hospitals.

I ask you to pass the amending language in S.B. 402.

Thank you

Senate P. H&W
Attachment 5
3-16-93

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 16, 1993

Testimony on SB 410

To: Chairperson Praeger and Members, Senate Public Health Committee

From: Harold Riehm, Executive Director, Kansas Assoc. 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 utilitization 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 icnreasing 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 and 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.

Senate PH&W
attachment #6
3-16-93

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

March 16, 1993
Topeka, Kansas

Madam Chair and members of the Committee. My name is Margot Gendreau Lenzi and I am appearing before you today in my capacity as 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 passed in 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 board to assist the state by providing educational information on drug usage and by conducting prospective and retrospective utilization review.

Currently SRS operates a DUR Committee. Senate Bill 410 establishes a DUR Board, advisory to SRS, and sets out the makeup of that Board, consistent with the federal requirements of OBRA 90.

Senate PH&W
attachment 7
3-16-93

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 education 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 specifies that the DUR Board would not be subject to the state open meetings act when considering patient

profile information or matters relating to identifiable providers. When the Board is considering policy matters, the process would be open to the public just as with other advisory boards and commissions and just as it is with the legislative process. 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.

impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), the amended regulation, therefore, is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

Although the amended regulation will affect some small entities, this certification can be made because VA believes that the overwhelming majority of small entities have already submitted all the necessary periodic certifications. The department does not believe that requiring the remainder to submit them before October 1, 1993 will cause a significant economic impact. Therefore, the amended regulation will have no significant economic impact on small entities, i.e., small businesses, small private and nonprofit organizations and small governmental jurisdictions.

The Catalog of Federal Domestic Assistance number for the program affected by this regulation is 64.121.

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: September 15, 1992.

Edward J. Derwinski,

Secretary of Veterans Affairs.

PART 21—VOCATIONAL REHABILITATION AND EDUCATION

Subpart F–1—Veterans' Job Training

For the reasons set out in the preamble, 38 CFR part 21, subpart F–1 is amended as set forth below.

1. The authority citation for part 21, subpart F–1 continues to read as follows:

Authority: Pub. L. 98–77, 97 Stat. 443.

In § 21.4632 paragraph (c)(4) and its authority citation are added to read as follows.

§ 21.4632 Payment restrictions.

* * * * *

(c) *Release of payments.* * * *

(4) VA will not release any payments for training provided by an employer if VA receives the employer's certification for that training after September 30, 1993.

(Authority: Sec. 8, Pub. L. 98–77, 97 Stat. 443)

* * * * *

[FR Doc. 92–28453 Filed 10–30–92; 8:45 am]

BILLING CODE 8320–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 456

[MB–050–IFC]

RIN 0938–AF67

Medicaid Program; Drug Use Review Program and Electronic Claims Management System for Outpatient Drug Claims

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim rule implements provisions of section 4401 of the Omnibus Budget Reconciliation Act of 1990 by specifying requirements for a Drug Use Review program, including the establishment of Drug Use Review Boards, and for an Electronic Claims Management system for outpatient drugs.

DATES: *Effective date:* These regulations are effective on January 1, 1993.

Comment period: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 4, 1993.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB–050–IFC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code MB–050–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 245–7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit comments to: Laura Oliven, HCFA Desk Officer, Office of Informatio Regulatory Affairs, Room 30 Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Thomas Fulda, (410) 966–3343.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Title XIX the Social Security Act (the Act) authorizes grants to States for medical assistance (Medicaid) to needy individuals. The Medicaid program is jointly financed by the Federal and State governments and administered by the States. Within Federal rules, each State decides eligible groups, types and ranges of services, payment levels for most services, and administrative and operating procedures. A State submits to HCFA a written statement, called a State plan, that describes the nature and scope of its Medicaid program. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program. The plan is amended whenever necessary to reflect changes in Federal or State law, changes in policy, or court decisions.

B. Legislative Background

Under section 1905(a)(12) of the Act, States may provide coverage of outpatient prescription drugs as an optional service. Section 1903(a) of the Act provides for FFP in State expenditures for these drugs. Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) redesignated section 1927 of the Act as section 1928 and added a new section 1927 to the Act.

Section 1927(g) of the Act provides that, for FFP payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, not later than January 1, 1993, a drug use review (DUR) program that consists of prospective drug review, retrospective drug use review, the application of explicit predetermined standards, and an educational program. The purpose of the DUR program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and that they are not likely to result in adverse medical results. Section 1927(g)(1)(A) of the Act directs that the program be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of

d. abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients or associated with specific drugs or groups of drugs. Section 1927(g)(1)(B) of the Act requires that the program assess data on drug use against predetermined standards consistent with peer-reviewed literature and three specified compendia. The assessment must include, but is 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.

Section 1927(g)(1)(C) of the Act specifies that the Secretary must pay to each State 75 percent of the sums expended by the State plan during calendar years 1991 through 1993 that the Secretary determines are attributable to the Statewide adoption of a DUR program that conforms to the statutory requirements.

Section 1927(g)(1)(D) of the Act specifies that States are not required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures currently at 42 CFR 483.60.

Section 1927(g)(2)(A) of the Act contains the requirements for prospective drug review. The statute requires that the State plan provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under the Medicaid program. The review must include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

Section 1927(g)(2)(A)(ii) of the Act requires that, as part of the prospective drug review program, applicable State law establish standards for counseling of Medicaid recipients by pharmacists. The statute directs that State law must require pharmacists to offer to discuss, with each recipient or caregiver who presents a prescription, matters that the pharmacist, exercising his or her professional judgment (consistent with State law respecting the providing of such information), deems significant, including specified information. The statute requires that the discussion be in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls. The statute does not require that a pharmacist provide consultation when a recipient or the recipient's caregiver refuses the consultation. The statute further requires the pharmacist to make a reasonable effort to obtain, record, and maintain specific patient profile information.

Section 1927(g)(2)(B) of the Act contains the requirements for retrospective drug use review. It requires that the DUR program provide 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 Medicaid benefits, or associated with specific drugs or groups of drugs.

Section 1927(g)(2)(C) of the Act requires that the DUR program assess data on drug use against explicit predetermined standards. It also requires that, as necessary, the program introduce remedial strategies to improve the quality of care and to conserve Medicare funds or personal expenditures.

Section 1927(g)(2)(D) of the Act requires that, in order to improve prescribing or dispensing practices, States provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems.

Section 1927(g)(3) of the Act requires that States establish a DUR Board, either directly or through contract with a private organization. It contains requirements regarding the qualifications of Board members and the composition of the Board and specifies the activities of the Board. It also requires the State to prepare an annual report for submission to the Secretary that describes the activities of the DUR Board, including specified information.

Section 1927(h) of the Act requires the Secretary to encourage each State Medicaid agency to establish a point-of-sale electronic claims management (ECM) system for processing claims for covered outpatient drugs. The ECM system must be capable of performing on-line, real-time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists and other authorized persons in applying for and receiving payment. The statute specifies that, if the State acquires, through applicable competitive procurement process, the most cost-effective telecommunications network and automatic data processing services and equipment, FFP at a matching of 90 percent will be made for expenditures made in calendar quarters during fiscal years 1991 and 1992 for the development of the ECM system.

Section 1927(j) of the Act exempts covered outpatient drugs dispensed by health maintenance organizations from the requirements of section 1927 of the Act. Section 1927(j) further requires that the State plan provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of section 1927 of the Act.

II. Provisions of this Interim Rule

In developing these regulations, we have essentially relied on the language of sections 1927(g) and (h) of the Act as established by Public Law 101-508. We also sought and received advice from various national provider associations, States, pharmaceutical companies, drug utilization review firms, and others. We considered their comments as we developed this interim rule.

Note that sections 1927(g) and (h) of the Act use the term "drug use review" to describe the total program (prospective review, retrospective review, and education) and in speaking of the retrospective review activity. These same sections use the term "drug review" to mean the prospective review activity. We maintain that distinction in terminology in the following discussion.

A. Scope of Regulations

Current regulations at § 456.1 set forth the basis and purpose of 42 CFR part 456, "Utilization Control." We have revised § 456.1(a) to add that part 456 prescribes specific requirements for an outpatient DUR program. We have revised § 456.1(b), which lists the statutory basis for the requirements in part 456, by adding the statutory basis for the DUR program. We have also revised Table 1, which shows the relationship between sections of the Act and the requirements of part 456, to include this information for subparts J and K of part 456. Subpart J has been in existing regulations, but, through an apparent oversight, it was not included in the table. As discussed below, subpart K is being added to part 456 by this rule.

We are establishing a new subpart K, entitled "Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims," in part 456. In § 456.700, we set forth the scope of this subpart.

We state that this subpart prescribes requirements for—

- An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;
- The establishment, composition, and functions of a State DUR Board; and
- An optional point-of-sale ECM system for processing claims for covered outpatient drugs.

B. Definitions

In § 456.702, we define the following terms for purposes of subpart K of part 456, using definitions already established in regulations:

- Abuse—as currently defined in § 455.2.
- Criteria—as currently defined in § 466.1.
- Fraud—as currently defined in § 455.2.
- Standards—as currently defined in § 466.1.

In addition, we have established the following definitions in § 456.702:

- "Adverse medical result" means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.
- "Appropriate and medically necessary" means drug prescribing and dispensing that is in conformity with predetermined standards established in accordance with § 456.703.
- "Gross overuse" means repetitive overutilization without therapeutic benefit.
- "Inappropriate and medically unnecessary" means drug prescribing and dispensing not in conformity with the definition of "appropriate and medically necessary."
- "Overutilization" means use of a drug in quantities or for durations that put the recipient at risk of an adverse medical result.
- "Predetermined standards" means criteria and standards, as defined in this section [§ 456.702], that have been established in accordance with the requirements of § 456.703.
- "Underutilization" means that a drug is used by a recipient in insufficient quantity to achieve a desired therapeutic goal.

We believe that the definitions of "adverse medical result," "overutilization," "underutilization," and "gross overuse" reflect the meaning generally given these terms by the health care community. The definitions of "appropriate and medically necessary," and "inappropriate and medically unnecessary" define these terms in relation to predetermined standards established in accordance with this rule. We believe that, by including both criteria and standards in the definition of "predetermined standards," we provide a framework for drug therapy guidelines, while allowing State Medicaid programs adequate flexibility to accommodate legitimate variations in prescribing practices.

Other terms are defined in the regulation sections in which they are used and are discussed in this preamble when discussing the contents of those sections.

C. Drug Use Review Program

In § 456.703(a), we specify that, in order for FFP to be paid under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of subpart K. This is based on section 1927(g) of the Act, which requires the establishment of a DUR program. We further specify that 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.

In § 456.703(b), we specify that prospective drug review and retrospective drug use review under the DUR program (including interventions and education) is not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in 42 CFR part 483. Note that this exception applies to the drugs, not to the pharmacies that dispense them. This provision for the rule is based on section 1927(g)(1)(D) of the Act, which specifies that States shall not be required to perform additional drug use review with respect to these drugs. We also specify, in accordance with the exemption at section 1927(j)(1) of the Act, that prospective drug review and retrospective drug use review are not required for drugs dispensed by health maintenance organizations (HMOs). These exemptions, however, do not affect the State's right to impose additional requirements. Therefore, we specify that the State is not precluded from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State makes the drugs subject to all the requirements applicable to the type of review. (Note further, that the term "covered outpatient drugs" is generally defined at section 1927(k)(2) of the Act, subject to the limitation at section 1927(k)(3), which, among other exclusions, excludes from the definition those drugs included in the per diem rate of nursing facilities. Thus, review under th program is not required for such ... Again, this does not preclude the State from making such drugs subject to DUR. Such review, however, would not be considered a part of the DUR program required by this subsection.)

In § 456.703(c), we require that the State plan provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. This reflects the requirement in section 1927(j)(2) of the Act.

In § 456.703(d), we specify, based on the requirement in section 1927(g)(1)(B) of the Act, that prospective drug review must assess drug use information against predetermined standards. In § 456.703(e), we specify that acceptable sources of predetermined standards are those—

- Developed directly by the State or its contractor;
- Obtained by the State through contracts with commercial vendors of DUR services;
- Obtained by the State from independent organizations, such as the United States Pharmacopeial Convention, or entities receiving funding provided by the Agency for Health Care Policy and Research (an agency of the Public Health Service), HCFA, or State agencies; or
- Any combination of the above.

We specify, in § 456.703(f), that the predetermined standards used in the DUR program must meet the following requirements:

1. The source materials for their development must be consistent with the peer-reviewed medical literature and the following compendia:

—American Hospital Formulary Service Drug Information.
—United States Pharmacopeia-Drug Information.
—American Medical Association Drug Evaluations. We define "peer-reviewed medical literature" as scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts.

2. Differences between source materials were resolved by physicians and pharmacists developing consensus solutions.

3. They are non-proprietary and readily available to providers of service. Systems and algorithms using the

determined standards may remain proprietary.

4. They are clinically-based and scientifically valid.

5. Retrospective review based on clinical criteria uses predetermined standards to determine the population at risk and applies standards, appropriate to this population, across providers to determine the provider outliers whose prescribing practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these outliers.

6. They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems.

7. The predetermined standards for prospective and retrospective DUR are compatible.

8. They are subjected to ongoing evaluation and modification either as a result of actions by their developers or as a result of recommendations by the DUR Board.

The first requirement reflects the language of section 1927(g)(1)(B) of the Act, with the addition of a definition of "peer-reviewed literature." We believe that our definition is how this term is commonly understood. The second requirement takes into consideration the possibility that there may be differences between the compendia and peer-reviewed literature. The use by the developers of a professional consensus process involving pharmacists and physicians provides a means to resolve these differences. We believe providers should know what standards they are being judged against; therefore, we have included the third requirement. The fourth requirement recognizes the fact that criteria that are not scientifically valid and clinically-based would be substantively flawed and would be hard to apply to and unacceptable to clinicians. We established the fifth requirement because we believe there is a need to make clear that standards should not be used to decide what prescribing/dispensing practices are potential therapeutic problems. Clinical criteria are the appropriate basis for such decisions. Nonetheless, standards may be considered in deciding whether to intervene once the universe of potential therapeutic problems has been identified through the use of clinical criteria.

We established requirement number 6 because we believe testing is needed to determine the likely rate of problems to be uncovered by the use of a standard. If use of a particular standard results in an unusually large number of cases being identified as potential problems, it may be that the standard is not sufficiently precise to identify truly significant problems. We have established requirement number 7 because if prospective and retrospective predetermined standards are obtained from different sources, they might contain different recommendations. We established requirement number 8 because it is expected that experience and changes in the state of medical knowledge will make modification or elimination of predetermined standards or the addition of new ones necessary.

We believe that, as part of the educational process, providers should know against what predetermined standards they are being judged. We believe the general public also has a right to know what predetermined standards are being applied. Therefore, in addition to the requirement in § 456.703(f)(3) that the predetermined standards be non-proprietary, in § 456.703(g), we specify that, upon their adoption, predetermined standards must be available to the public and that pharmacists and physicians must be informed about how they can obtain copies.

Section 1927(g)(3)(c) of the Act indicates that, as part of conducting educational interventions, written, oral, and electronic reminders containing patient-specific and drug-specific information should be used. It also specifies that these messages must be communicated in a manner designed to ensure the privacy of patient-related information. Because of this provision and the broader issue of patient confidentiality associated with conducting DUR through an electronic claims management system, we require, in § 456.703(h), that the State establish, in regulations or through other means, policies concerning confidentiality of patient-related data that are consistent with the applicable Federal confidentiality requirements of subpart F of part 431, the State Pharmacy Practice Act, and guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies. It should be noted that Federal confidentiality requirements would not apply to patient profile requirements at § 456.705(d) of this rule.

D. Prospective Drug Review (Point-of-sale or Point-of-Distribution Drug Review and Counseling Requirements)

Section 456.705 sets forth the requirements for prospective drug review, based on the prospective drug review requirements of section 1927(g)(2)(A) of the Act. In paragraph (a), we specify that the State plan must provide for review of drug therapy before each prescription (other than those for drugs for certain nursing facility residents, drugs dispensed by HMOs, and certain covered outpatient drugs dispensed by hospitals) is filled or delivered to a recipient and that applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. We further require that the State provide pharmacies with detailed information as to what they must do to comply with prospective drug review requirements, including guidelines on counseling, profiling, and documentation of prospective drug review activities by the pharmacists. We specify that this information is to be based on guidelines provided by part 456, subpart K and other sources that the State may specify. We specify that the pharmacies, in turn, must provide this information to their pharmacists.

In § 456.705(b), we specify that the State plan must provide for point-of-sale or point-of-distribution review of drug therapy before each prescription is filled or delivered to the recipient or the recipient's caregiver. In accordance with the exceptions provided in sections 1927(g)(1)(D), 1927(j)(1), and 1927(j)(2) of the Act, we provide exceptions to this requirement for the following drugs, respectively:

- Drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in 42 CFR part 483.
- Drugs dispensed by HMOs.
- Covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs.

We specify that the review must include screening for potential drug therapy problems because of therapeutic duplication, drug-disease contraindication, adverse drug-drug interaction, incorrect drug dosage, incorrect duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. These requirements reflect the provisions of section 1927(g)(2)(A) of the Act. We recognize that screening for these drug therapy problems will be done without direct access to diagnosis information and details about disease conditions contained in medical records available in an inpatient environment. A pharmacist conducting prospective DUR can use the patient profile to obtain information from the patient about allergies, disease condition, and other

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levant information. In addition, based upon his or her professional judgment, the pharmacist may consult a physician(s), when appropriate, to obtain additional information. We do not believe the pharmacist will incur additional liability as a result of performing prospective DUR.

While the statute does not define "therapeutic duplication," "drug-disease contraindication," "adverse drug-drug interaction," "incorrect drug dosage," "incorrect duration of drug treatment," "drug-allergy interactions," and "clinical abuse/misuse," we describe these terms in § 456.705(b), based on what we believe are the meanings generally given these terms by the health care community. We describe these terms as follows:

- "Therapeutic duplication"—the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.
- "Drug-disease contraindication"—the potential for, or the occurrence of, an undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition or the potential for, or the occurrence of, an adverse effect of the drug on the patient's disease condition.
- "Adverse drug-drug interaction"—the potential for, or occurrence of, an adverse medical effect as a result of the recipient using two or more drugs together.
- "Incorrect drug dosage"—the dosage lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days supply.
- "Incorrect duration of drug treatment"—the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.
- "Drug-allergy interactions"—the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.
- "Clinical abuse/misuse"—the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in § 456.702, and incorrect dosage and duration, as defined in paragraphs (b)(4) and (b)(5) [of § 456.705], respectively.

In accordance with the counseling requirements of section 1927(g)(2)(A)(ii) of the Act, we require, in § 456.705(c), that standards for counseling by pharmacists of recipients or the recipients' caregivers be established by State law or other method that is satisfactory to the State. We believe that the standards should address questions such as whether an offer to counsel must be oral; whether or not posted signs may substitute for an oral offer to counsel; the applicability of this requirement to new and refill prescriptions; and the extent to which written material may or may not be substituted for the oral provision of information. Because we believe that the special nature of mail order pharmacy operations requires clarification as to how the counseling requirements apply to those entities, we require that the State law or State Medicaid agency policy include such clarification. We specify that the standards must meet the following requirements:

1. They require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. The standards need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses such consultation. The standards must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

2. They specify that the counseling include those matters listed below that, in the exercise of his or her professional judgment (consistent with State law regarding the provision of such information), the pharmacist considers significant, as well as other matters the pharmacist considers significant.

- The name and description of the medication.
- The dosage form, dosage, route of administration, and duration of drug therapy.
- Special directions and precautions for preparation, administration, and use by the patient.
- 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.
- Techniques for self-monitoring drug therapy.
- Proper storage.
- Prescription refill information.
- Action to be taken in the event of a missed dose.

Note that although section 1927(g)(2)(A)(ii)(I)(b) of the Act includes, in the list of matters to be discussed, both "route" and "route of administration," we believe the use of both terms is redundant. Therefore, we include "route of administration" but not "route" in the regulation.

Consistent with the recordkeeping requirements of section 1927(g)(2)(A) of the Act, we specify, in § 456.705(d), that the State must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing at least the following information:

- Name, address, telephone number, date of birth (or age), and gender of the patient.
- Individual medical history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
- Pharmacist's comments relevant to the individual's drug therapy.

We have not defined "reasonable effort" in the above context. It is the responsibility of the State, through the State Board of Pharmacy or, in the absence of such effort, the State Medicaid program's DUR Board to define "reasonable effort."

E. Retrospective Drug Use Review

Section 456.709 sets forth the requirements for retrospective DUR, based on the retrospective DUR requirements of section 1927(g)(2)(B) of the Act and the application of standards requirements of section 1927(g)(2)(C). In paragraph (a), we require that the State plan provide for the establishment of a retrospective DUR program for 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 Medicaid recipients, or associated with specific drugs or groups of drugs. We specify that this examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. We also specify that this periodic examination must occur no less frequently than quarterly. Quarterly processing is the usual Medicaid agency practice to support postpayment utilization review activities. It facilitates the timely accomplishment of educational interventions.

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...ion 1927(g)(2)(B) of the Act further states that the examination of claims data is to be made through the mechanized drug claims processing and information retrieval systems "or otherwise". We interpret "mechanized drug claims processing and information retrieval systems" to include both the Medicaid Management Information System (MMIS) and separate electronic drug claims processing systems that are integrated with MMIS. Accordingly, we further require in § 456.709(a) that retrospective review be provided through the State's mechanized drug claims processing and information retrieval system (that is, MMIS) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use their existing systems provided that the results of the examination of drug claims as described in this section are integrated with their existing claims processing system. However, we request comments to provide a basis for defining "or otherwise" as used in the statute.

In paragraph (b), we specify that retrospective DUR includes, but is not limited to, using predeterminated standards to monitor for the following:

- Therapeutic appropriateness.
- Overutilization and underutilization.
- Appropriate use of generic products.
- Therapeutic duplication.
- Drug-disease contraindication.
- Drug-drug interaction.
- Incorrect drug dosage.
- Incorrect duration of drug treatment.
- Clinical abuse or misuse.

We specify that "therapeutic appropriateness" is drug prescribing and dispensing that is in conformity with the predetermined standards. We specify that "appropriate use of generic products" is use of such products in conformity with State product selection laws. We believe these definitions reflect the meanings generally given these terms.

F. Educational Program

In § 456.711, we require that the State plan provide for ongoing educational outreach programs that educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. We specify that the program may be established by the DUR Board directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists' associations/societies, or other organizations. We further specify that the program must include, in appropriate instances, the following types of interventions:

- Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards used in assessing drug use.
- Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.
- Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.
- Intensified review or monitoring of selected prescribers or dispensers.

We specify that the DUR Board determines the content of education regarding common therapy problems and circumstances in which each of the interventions specified in § 456.711 (a) through (d) is to be used. These requirements are based on the requirements contained in sections 1927(g)(2)(D) and 1927(g)(3)(C)(iii) of the Act. The Medicaid agency is responsible for the education programs and for the actual interventions. The education and intervention functions may be carried out by a contractor responsible for retrospective DUR or by a contractor responsible for the DUR Board. It is left to State discretion as to whether the education and intervention functions are to be carried out by the same contractor or different contractors.

G. Annual report

In § 456.712(a), we specify, in accordance with section 1927(g)(3)(D) of the Act, that the State must require the DUR Board to prepare and submit, on an annual basis, a report to the Medicaid agency that contains information specified by the State.

In § 456.712(b) we specify that the Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at § 456.703(f) and with the access to the predetermined standards requirement at § 456.703(g).

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization review (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and the State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

We have included some requirements regarding the content of the annual report submitted to the Secretary not specified in the statute, in order to carry out the stated requirements effectively and efficiently. We ask for specifics about criteria and standards in use in order to have access to data that would make possible a national, as opposed to a State, evaluation of criteria. Conducting such a national evaluation would be done either by HCFA or outside researchers. We ask for clarification of the DUR and SUR review relationship. The retrospective DUR

requirements in section 1927(g)(2)(B) of the Act and in § 456.709 of this rule parallel a portion of the surveillance and utilization review (SUR) requirements in parts 455 and 456. Both programs address fraud, abuse, and quality of care issues. Both programs also use reports generated by automated systems approved by the Secretary under section 1903(r) of the Act. The overlapping responsibilities between the DUR program and the SUR program and the relationship between the two functions require clarification. With regard to the estimate of cost savings attributable to the DUR program (item 10 above), this estimate must take into account savings to the pharmacy budget, savings resulting from changes in physicians' visits, and changes in hospital costs.

The statute assigns responsibility for preparation of the full report to the State, based on information provided by the Board's report. We expect that the State will make the Board responsible for providing information to the Medicaid agency on those areas where its particular professional expertise makes it the suitable source of the information. For example, the DUR Board may be the appropriate source for the information in items 2, 3, 6, and 7 above.

H. DUR Boards

Section 456.716 sets forth the requirements for State DUR Boards, based on the requirements regarding these Boards contained in sections 1927(g)(2)(D) and 1927(g)(3) of the Act. In paragraph (a), we require each State to establish, either directly or through a contract with a private organization, a DUR Board. We require that the Board include health care professionals who have recognized knowledge and expertise in at least one of the following:

- Clinically appropriate prescribing of covered outpatient drugs.
- Clinically appropriate dispensing and monitoring of covered outpatient drugs.
- Drug use review, evaluation, and intervention.
- Medical quality assurance.

In paragraph (b), we require that at least one-third but not more than 51 percent of the DUR Board members be physicians and that at least one-third of the Board members be pharmacists. We further require that these physicians and pharmacists be actively practicing and licensed by the State on whose DUR Board they are serving. While the statute does not specify the source of the license, we are requiring that the licensure be "by the State on whose DUR Board they are serving" because we believe that professionals who are involved in the provision of pharmaceutical care in the State would have a greater interest in the activities of the Board than individuals from outside the State.

In paragraph (c), we clarify the relationship between the Medicaid agency and the DUR Board. We specify that the Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of part 456, subpart K, and that it has the authority to accept or reject the recommendations or decisions of the Board.

In paragraph (d), we specify that the State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. We further specify that, except as limited by section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationship we set forth in § 456.716. Section 1927(g)(3)(C) of the Act assigns three activities to the Board: Retrospective DUR, application of predetermined standards, and ongoing interventions. Section 1927(g)(2)(D) of the Act requires that the DUR program, through the DUR Board, provide for educational outreach programs (including interventions). Section 1927(g)(3)(D) of the Act specifies that the State must require the Board to submit a report to it on an annual basis. Section 1927(g)(1) of the Act, however, leaves to the State the overall responsibility for ensuring that the DUR program is operational and comports with all requirements for FFP. Therefore, the Medicaid agency must retain the authority to accept or reject the recommendations of the DUR Board, particularly on matters not given to the Board by the statute. Additionally, there are operational areas, such as the daily operation of the DUR portion of the MMIS system and intensified review or monitoring of selected prescribers or dispensers, that we suggest are more appropriately assigned to the Medicaid agency. In setting forth the activities of the Board and the Medicaid agency in § 456.716(d), we accommodate both the statutory dictates and the operational concerns. In those areas that are assigned to the Board by the statute, we suggest a division of labor under which the Board is responsible for those areas that require its expertise in medicine and pharmacy and the Medicaid agency is responsible for those areas requiring its expertise in the ongoing o[illegible] as of the program.

With regard to the application of predetermined standards, we suggest that the Board perform the following activities:

- Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.
- Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.
- Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective drug review.

We request comments on whether the DUR Board should evaluate DUR software available to pharmacies to determine whether it enables pharmacies to meet the requirements of prospective review and advise the Medicaid agency or its contractor concerning software acceptable for use by pharmacies in conducting prospective drug review.

We suggest that the Medicaid agency or its contractor perform the following activities related to application of predetermined standards:

- Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.
- If prospective drug review is conducted using an electronic claims management (ECM) system, apply software recommended by the Board.
- If prospective drug review is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(2)(A) of the Act.

We request comments as to whether the Medicaid agency (or its contractor) should disseminate to pharmacies information concerning prospective drug review software provided to it by the Board.

With regard to retrospective DUR, we suggest that the DUR Board perform the following activities:

- Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

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• Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

With regard to retrospective DUR, we suggest that the Medicaid agency or its contractor apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

With regard to the education program (including interventions), we suggest that the Board perform the following activities:

• Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.

• Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy.

• Periodically re-evaluate and, if necessary, modify the interventions.

With regard to the education program (including interventions), we suggest that the Medicaid agency or its contractor perform the following activities:

• Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and intervention and furnish those reports to the Board.

• Carry out the educational programs and interventions specified by the Board.

In § 456.718(e), we specify that FFP is available for expenses associated with the operation of the DUR Board at the rate of 75 percent for funds expended by the State during calendar years 1991 through 1993. This is in accordance with the funding provision of section 1927(g)(1)(C) of the Act. We also specify that, after December 31, 1993, if the requirements for skilled professional medical personnel set forth in § 432.50 are met, FFP is available at the rate established by that section, that is, a rate of 75 percent. If the requirements for skilled professional medical personnel are not met, we specify, in accordance with the rate established at § 433.32(b)(7), that the rate for funds expended after December 31, 1993 is 50 percent.

I. Funding of DUR Program

Based on the funding provision of section 1927(g)(1)(C) of the Act, we specify, in § 456.719, that FFP is available at the rate of 75 percent for sums that the Secretary determines are attributable to the Statewide adoption of a DUR program as described in subpart K and that were expended by the State during calendar years 1991 through 1993. We further specify, in accordance with the rate established at § 433.32(b)(7), that the rate for funds expended by the State after December 31, 1993, is 50 percent. We specify that payment is made under procedures established in part 433.

J. Electronic Claims Management System

Section 456.722 sets forth the requirements for an ECM system, based on section 1927(h) of the Act. Section 1927(h) requires the Secretary to encourage each Medicaid agency to establish, as its principal means of processing claims for covered outpatient drugs, a point-of-sale ECM system and contains requirements for such a system.

In paragraph (a), we specify that each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale ECM system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The ECM systems should assist pharmacists in applying for and receiving payment by electronically providing information, at point of sale, as to whether the recipient is eligible, the drug is covered, etc., thereby facilitating payment of claims. Since the statute specifies that the ECM system is to be the "principal" (not exclusive) means of processing claims, universal participation in the system is not required. Who must participate in an ECM system is to be determined by the State. Therefore, we also specify, in paragraph (a), that the State makes this determination. We further specify that, if the State exercises the option to establish an ECM system and wishes to receive FFP for its system, the system must meet the functional and additional procurement and system requirements discussed below. We request comments on how and to what extent these ECM requirements may affect the use of existing automated systems, the use of alternative techniques, such as "smart cards," and the participation of pharmacies in the Medicaid drug program.

In paragraph (b), we require that the ECM system developed by the State must include at least the following on-line, real-time capabilities:

• Eligibility verification, including identification of the following:
—Third-party payers.
—Recipients in managed care programs.
—Recipients and providers in restricted service programs (for example, lock-in and lock-out).
—Properly-enrolled providers.

• Claims data capture, including the following:
—Processing of prescription drug claims.
—Identification of prescriber.
—Minimum data set for claims (as defined in Part 11 of the State Medicaid Manual).

• Claims adjudication, including the following:
—Performing all edits and audits contained in the State's MMIS applicable to prescription drugs.
—Notifying the pharmacist (or another authorized person, such as the dispensing physician) about the claim status.
—Taking steps up to but not including, payment of the claim.

We provide that the real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State and claims may be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and the Medicaid agency. We provide this waiver because the large volume of claims from mail order and nursing home pharmacies make on-line, real-time processing impractical. It should be noted that, if the State allows batch claims processing, this does not exempt the pharmacy from any other requirements of this subpart.

In paragraph (c), we specify that in order to receive FFP for its ECM system, the State must meet the following requirements:

• The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G–O of OMB circular A–102. In accordance with section 1927(h)(2)(B) of the Act, we permit the substitution of a request for proposal (RFP) for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 95.205, and 45 CFR part 307. We require that a cost-benefit analysis accompany the RFP. Also, we provide that, if in its advance planning document a State establishes

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that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, we specify that network services and equipment (but not software modifications) that are available from a variety of sources be competitively procured.

We also specify that States wishing to do prospective drug review as part of their ECM must do the following:

- Submit a cost benefit analysis showing the cost-effectiveness of such a system. We also require that State decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.
- Establish a central State-wide electronic repository for capturing, storing, and updating data for all prescriptions dispensed and for providing access to such data by all authorized participants.
- Design the system to assess data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in § 456.705.

We also specify that ECM is considered a subsystem of the MMIS and must be fully integrated with other components of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

States developing ECM systems are strongly encouraged, but not required, to design their systems to receive and progress claims formatted according to the recommended Medicaid transaction data set of the Telecommunication Standard Format, Version 3.2, as issued by the National Council for Prescription Programs.

In § 456.725(a), we specify, as provided in section 1927(h)(2)(1)(A) of the Act, that for funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management system that meets the requirements of § 456.722, FFP is available at a matching rate of 90 percent. We further specify that after fiscal year 1992 ECM subsystems will be funded at the standard applicable MMIS enhanced rates, subject to the requirements in part 433, subpart A.

Based on the Federal matching provisions in part 433, subpart A, we specify, in § 456.725(b), that FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.

III. Regulatory Impact Analysis

Executive Order 12291 (E.O. 12291) requires us to prepared and publish a regulatory impact analysis for any rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that will be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, will pharmacies and prescribing physicians are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We are not preparing a rural impact analysis since we have determined, and the Secretary certifies, that this interim final rule with comment will not have a significant impact on the operations of a substantial number of small rural hospitals.

This interim final rule with comment period constitutes a major rule since total costs are estimated to exceed $100 million annually. Also, we anticipate that a large percentage of pharmacists and prescribers will be affected. Therefore, the following discussion, in combination with the discussion presented in the preamble, constitutes a regulatory impact and regulatory flexibility analysis.

A. Background

A primary purpose of the DUR program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The statute also directs that the DUR program be designed to educate physicians and pharmacists on common drug therapy problems and assessments of whether usage complies with predetermined standards.

Additionally, the Congressional Budget Office estimated that annual total Federal and State savings as a result of the DUR provisions of Public Law 101-508 will be in the $10 million to $40 million range. This savings is the result of an expected reduction in the number of prescriptions written and dispensed. We welcome comments concerning savings that States may expect from implementation of DUR requirements.

B. Impact on Pharmacies

Most of the work and responsibility for implementing a meaningful DUR program will fall upon the estimated 58,000 retail pharmacies in the United States, virtually all of which participate in the Medicaid program. During 1991, pharmacy payments from the Medicaid program totaled approximately $5.5 billion, approximately 17 percent of the total revenue for prescription drugs. For some pharmacies, depending upon the pharmacy's location and the number of Medicaid recipients in the area, the Medicaid program payments represent a significant portion of their total pharmacy income.

1. Prospective Drug Review and Counseling

Section 1927(g)(2)(A) of the Act requires the State plan to provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. Unless the State adopts an optional point-of-sale electronic claims management (ECM) system that includes prospective drug

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ew where prospective screening is
e at the State level, prospective drug review screening will be done by individual pharmacies. Pharmacists will either have to rely on approved prospective drug review software programs or rely on written criteria, approved by the State, to properly perform manual prospective drug review.

Though an estimated 85 percent of pharmacies use computers, results of a survey of 12,456 pharmacists conducted in 1991 by the National Pharmacy Forum on Medicaid Drug Amendments showed significant differences in their ability to use computers for prospective DUR screening. The majority of pharmacists, for example, reported in that survey that they were able to screen for drug-drug interactions (85.6 percent), and drug-allergy interactions (82.2 percent) but very few pharmacists reported that they were able to screen for incorrect drug dosage (16.0 percent) and drug-disease contraindication (29.2 percent). Overall, 55 percent of the pharmacists surveyed indicated that they could not use their computers to screen for six of the nine types of prospective DUR screening required by OBRA 1990. The great majority of pharmacists will, as a result, have to update their prospective DUR software to meet the statutory requirements. We estimate the one time cost of upgrading prospective DUR software to be between $1000 and $2000 for the average pharmacy. In the event that the pharmacy's computer is not adequate to handle the demands of prospective DUR software, the pharmacy may also have to upgrade or replace their computer hardware. The $1000 to $2000 original estimate does not include any costs associated with upgrading the computer hardware. The majority of pharmacies have computers which are used for billing purposes, inventory control, prescription pricing, printing of the prescription labels, and generating handout information concerning drug interactions. The estimated initial cost for these computer systems is $12,000 to $15,000. Special computer programs, linking multiple stores, could increase the initial costs. In general, we believe it is unlikely that many pharmacies will have to significantly change their entire computer system to meet these DUR requirements. We would like to receive comments or additional information on this issue. It should be noted that pharmacists not wishing to upgrade their computer software may conduct prospective DUR screening manually, which must be based on approved written standards that satisfactorily meet statutory requirements.

Section 1927(g)(2)(A)(ii) of the Act requires that applicable State law establish standards for counseling of recipients receiving prescriptions. The State law must require a pharmacist to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll free for long-distance calls), each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a toll free exchange, need not be required to offer toll free service. In addition, the State law must specify how counseling requirements apply to mail order pharmacies.

Little up to date information is available on the extent to which counseling is occurring in pharmacy practice. Seventeen States already require an offer of counseling by the pharmacist. Recent studies suggest that counseling occurs more frequently for new prescriptions than for refill prescriptions and that counseling is more frequent if done by a pharmacist than by a clerk. The effectiveness of counseling is also related to the training in counseling received by the pharmacist and the educational level of the recipient. At the present time we believe that counseling is provided for less than 50 percent of the total prescriptions dispensed and that the percentage of Medicaid recipients receiving counseling is lower than the general population.

The pharmacist must also make a reasonable effort to obtain and record patient information and maintain the patient profiles that are essential for the pharmacist to counsel the recipient concerning medication problems unique to the recipient. We expect that counseling and profiling requirements of OBRA 1990 will involve additional pharmacist time, which is costly. Our best estimate is that making the offer to counsel, reviewing a patient profile, and conducting counseling (exclusive of establishing a patient profile and interventions where the pharmacist takes an action such as telephoning the physician) could take two to four minutes at a cost of $1 to $2 per prescription. Assuming that counseling services are actually provided for 25 percent of all Medicaid prescriptions, and there are approximately 280 million Medicaid prescriptions filled each year, the annual cost for the pharmacists to provide this service is $70 million to $140 million. We would welcome comments with regard to the accuracy of this cost estimate.

2. Retrospective DUR and Educatic Outreach

Section 1927(g)(2)(B) of the Act contains the requirements for retrospective DUR. Nineteen states already have retrospective DUR programs. Retrospective DUR provides, through its mechanized drug claims processing and information retrieval systems, 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 pharmacy benefits. Costs of establishing retrospective DUR programs for those States which do not already have them will depend on the size of the State's drug program. We estimate that implementation of retrospective DUR could cost an average of $250,000 to $300,000 annually per State, for a total national cost of $12.5 million to $15 million annually. We welcome comments with regard to the accuracy of this estimate.

Section 1927(g)(2)(D) of the Act requires that the State DUR board, 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, provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices. The resulting intervention may involve written, oral, or electronic reminders containing patient-specific or drug-specific information along with suggested changes in prescribing or dispensing practices. Included will be face-to-face discussions, when appropriate and necessary, with prescribers and pharmacists who have been selected for educational intervention. The DUR Board will make policy recommendations concerning the circumstances under which each type of intervention will occur. We have no way of knowing how many practitioners will be selected for intervention or of knowing what types of intervention will be used. The level and type of intervention will determine the cost of the education/intervention component of retrospective DUR. We estimate that sending letters could cost from $5 to $8 each and more extensive encounters such as face-to-face interventions could cost as much as $200 per encounter. The costs to States will vary with the number of interventions and the type

necessary to perform effective retroactive DUR. We welcome comments on the accuracy of these estimates.

3. Impact on the Pharmacy Dispensing Fee

The requirements for DUR and counseling that Public Law 101–508 imposes on pharmacists will increase the costs of operating a pharmacy and be reflected by surveys conducted by States to determine the cost of filling a prescription. This increased cost of operating a pharmacy may result in pressure to raise dispensing fees. Since these fees are set by the States, the additional costs incurred by pharmacies will not necessarily translate directly or immediately into increased Federal Medicaid costs. Historically, Medicaid dispensing fees have grown slowly, an average of under 3 percent per year between 1985 and 1991. The rate of increase has been higher (4.45 percent) in the last 2 years as many States increased fees that had been level for a number of years. Given the current budget climate and the States' likely resistance to granting increases, the net impact on Medicaid program expenditures is not expected to be large. At current Medicaid drug program spending levels, every 1 percent increase in the average dispensing fee translates into an estimated $5 million to $10 million in additional Federal funding. Thus, if the provisions of Public Law 101–508 cause dispensing fees to rise 2 percentage points above the average, the impact could be on the order of $10 million to $20 million and could offset the expected range of savings due to DUR implementation.

C. Impact on Recipients

The primary impact of DUR on the recipient should be to improve the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, dispensing and use of prescription drugs. According to one study that reviewed several potentially problem drugs, up to 30 percent of the patients receiving prescriptions for these drugs received an inappropriate prescription. DUR will be expected to catch some of these problems, but not all of them. Individual pharmacy DUR will not catch problems if conflicting prescriptions are filled at different pharmacies nor will it catch problems resulting from beneficiaries taking medication found in the home originally prescribed for someone else. The majority of these inappropriate prescriptions do not entail a significant health risk to the patient but some inappropriate prescriptions, for various reasons, may be harmful or even potentially life threatening. Since DUR is an educational process, the benefit to the recipient should be a gradual reduction in the incidence of inappropriate prescribing and improved health outcomes for some beneficiaries. Since no reliable research data on likely benefits are known to us, we request information concerning this item. There may, however, be some reduction in pharmacy participation in the Medicaid program, resulting in some hardship on those beneficiaries who must travel longer distances to obtain pharmacy services.

D. Impact on States

States will incur increased costs to implement the DUR requirements of Public Law 101–508. Unless a State chooses to conduct prospective DUR as part of an optional ECM system, a State's cost for prospective DUR will be primarily for compliance monitoring and could cost approximately $50,000 per State except in the States such as California and New York that have large drug programs. State costs, in those States that do not have retrospective DUR in place already, should not exceed $250,000 to $300,000 per State, except in the States with large drug programs. As previously indicated, estimating the cost of educational intervention required by the statute is not possible without knowing the likely level of each type of intervention. States also have the option of establishing ECM systems and also of conducting prospective DUR as part of such systems. We welcome comments and cost information from States that have already implemented ECM systems that include prospective DUR or from States that have received cost estimates for implementing similar systems.

E. Conclusion

The provisions of this interim final rule with comment are required by section 4401 of OBRA 1990. We believe any discretion we have exercised in defining certain terms will not impose a significant burden on participating pharmacies and prescribing physicians, particularly in comparison to the costs mandated by the statute or costs which States may voluntarily elect to incur.

We do recognize that the provisions to offer counseling and to maintain profiles may impose some additional burden on those pharmacies that are not already performing similar tasks. In addition, responding to educational outreach may require some response time on the part of both physicians and pharmacists, but we believe all parties should benefit.

The impact on States w[illegible]y. The 31 States that do not yet have retrospective DUR programs will be required to initiate both retrospective and prospective drug review systems by January 1, 1993. The 19 States with retrospective DUR programs will have to implement some form of prospective drug review program to comply with this interim final regulation with comment.

This regulation leaves pharmacies free to conduct prospective drug review either electronically or manually. Further, with regard to the requirements for Federal matching funds for a State's ECM system, it allows an exception to the on-line, real time eligibility verification requirements to mail order pharmacies and for prescriptions filled for nursing facility residents. These exceptions are attempts to reduce the burden or unnecessary costs to pharmacies to meet the DUR program requirements. We specifically request comments on other ways to reduce costs or burdens on participating pharmacies.

IV. Waiver of Proposed Rulemaking

Because the Secretary is exercising discretion in implementing section 1927 (g) and (h) of the Act, ordinarily we would publish a notice of proposed rulemaking and afford a period for public comment. However, section 4207(j) of Public Law 101–508 permits the Secretary to issue interim final regulations to implement the provisions of that law. Because States need sufficient lead time to recruit DUR board members, release RFPs, pass the required legislation, etc., so that the DUR program can be in place as of January 1, 1993, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period for public comment.

V. Response to Comments

Because of the large number of items of correspondence we normally receive concerning regulations, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the "DATES" section of this preamble, and we will respond to the comments in the preamble of that rule.

VI. Collection of Information Requirement

Regulations at §§ 456.705(d) and 456.712 contain information collection or recordkeeping requirements or both that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44

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.C. 3501 et seq.). The information ..llection requirements concern the collection of information for patient profiles of Medicaid recipients, preparation by State DUR Boards of annual reports to the State agency, and preparation by the State agency of annual reports to the Secretary. These are statutory requirements. The respondents who will provide the information include Medicaid recipients, who will provide information for profiles to pharmacists, State DUR Boards that will provide annual report information to the States, and States that will provide annual reports to the Secretary. Public reporting burden for the collection of the profile information is estimated to be 5 minutes for each initial encounter and 2 minutes for each subsequent encounter. Public reporting burden for the collection of the annual report information, which includes activities by the DUR Board and by the State agency, is estimated to be up to 60 hours per year per State. A notice will be published in the Federal Register after approval is obtained.
Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the "ADDRESSES" section of this preamble.

List of Subjects in 42 CFR Part 456

Administrative practice and procedure, Grant Programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR part 456 is amended as set forth below:

PART 456—UTILIZATION CONTROL

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

2. In § 456.1, the introductory text of paragraph (a) is republished, a new paragraph (a)(3) is added, the introductory text of paragraph (b) is republished, a new paragraph (b)(8) is added, and the introductory text of Table 1 is republished and new subparts J and K are added to the table to read as follows:

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

* * * * *

(3) Specific requirements for an outpatient drug use review program.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

* * * * *

(8) *Drug use review program.* Section 1927(g) of the Act provides that, for payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a drug use review (DUR) program. It also requires that each State provide, either directly or through a contract with a private organization , for the establishment of a DUR Board.

Table 1

[This table relates the regulations in this part to the sections of the Act on which they are based.]

* * * * *

Subpart J—Penalty for Failure To Make a Satisfactory Showing of An Effective Institutional Utilization Control Program (1903(g))

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims (1927(g) and (h))

3. A new subpart K is added to part 456 to read as follows:

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

Sec.

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

§ 456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system for processing claims for covered outpatient drugs.

§ 456.702 Definitions.

For purposes of this subpart—

Abuse is defined as in § 455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with § 456.703.

Criteria is defined as in § 466.1 of this chapter.

Fraud is defined as in § 455.2 of this chapter.

Gross overuse means repetitive overutilization without therapeutic benefit.

Inappropriate and medically unnecessary means drug prescribing and dispensing not in conformity with the definition of *appropriate and medically necessary.*

Overutilization means use of a drug in quantities or for durations that put the recipient at risk of an adverse medical result.

Predetermined standards means criteria and standards that have been established in accordance with the requirements of § 456.703.

Standards is defined as in § 466.1 of this chapter.

Underutilization means that a drug is used by a recipient in insufficient quantity to achieve a desired therapeutic goal.

§ 456.703 Drug use review program.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. 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.

(b) *Exception for drugs dispensed to certain nursing facility residents and for drugs dispensed by health maintenance organizations.* Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of

nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter and for drugs dispensed by health maintenance organizations. This does not preclude the State from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals.* The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart.

(d) *Use of predetermined standards.* A DUR program must assess drug use information against predetermined standards.

(e) *Source of predetermined standards.* The predetermined standards must be—

(1) Developed directly by the State or its contractor;

(2) Obtained by the State through contracts with commercial vendors of DUR services;

(3) Obtained by the State from independent organizations, such as the United States Pharmacopeial Convention, or entities receiving funding from the Public Health Service, HCFA, or State agencies; or

(4) Any combination of paragraphs (f)(1) through (f)(3) of this section.

(f) *Requirements for predetermined standards.* The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts) and the following compendia:

(i) American Hospital Formulary Service Drug Information.

(ii) United States Pharmacopeia-Drug Information.

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions.

(3) They are non-proprietary and readily available to providers of services. Systems and algorithms using the predetermined standards may remain proprietary.

(4) They are clinically-based and scientifically valid.

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk and applies standards, appropriate to this population, across providers to determine the provider outliers whose prescribing practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these outliers.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems.

(7) The predetermined standards for prospective and retrospective DUR are compatible.

(8) They are subjected to ongoing evaluation and modification either as a result of actions by their developer or as a result of recommendations by the DUR Board.

(g) *Access to predetermined standards.* Upon their adoption, predetermined standards must be available to the public. Pharmacists and physicians must be informed of the existence of predetermined standards and of how they can obtain copies of them.

(h) *Confidentiality of patent-related data.* In implementing the DUR program, the State must establish, in regulations or through other means, policies concerning confidentiality of patent-related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F; the State Pharmacy Practice Act; and guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

§ 456.705 Prospective drug review.

(a) *General.* Except as provided in §§ 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The pharmacies, in turn, must provide this information to their pharmacists. This information is to be based on guidelines provided by this subpart and by other source the State may specify.

(b) *Point-of-sale or point-of-distribution review.* Except as provided in §§ 456.703 (b) and (c), the State plan must provide for point-of-sale or point-of-distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient's caregiver. The review must include screening to identify potential drug therapy problems of the following types:

(1) Therapeutic duplication, that is, the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

(2) Drug-disease contraindication, that is, the potential for, or the occurrence of—

(i) An undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition; or

(ii) An adverse effect of the drug on the patient's disease condition.

(3) Adverse drug-drug interaction, that is, the potential for, or occurrence of, an adverse medical effect as a result of the recipient using two or more drugs together.

(4) Incorrect drug dosage, that is, the dosage lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days supply.

(5) Incorrect duration of drug treatment, that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

(6) Drug-allergy interactions, that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

(7) Clinical abuse/misuse, that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in § 456.702, and incorrect dosage and incorrect duration, as defined in paragraphs (b)(4) and (b)(5) of this section, respectively.

(c) *Drug counseling.* As part of the prospective-drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State. The State law must specify how counseling requirements apply to mail

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order pharmacies. The standards must meet the following requirements:

(1) They require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. The standards need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses such consultation. The standards must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

(2) They specify that the counseling include those matters listed below that, in the exercise of his or her professional judgment (consistent with State law regarding the provision of such information), the pharmacist considers significant, as well as other matters the pharmacist considers significant.

(i) The name and description of the medication.

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

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

(iv) 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.

(v) Techniques for self-monitoring drug therapy.

(vi) Proper storage.

(vii) Prescription refill information.

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

(d) *Profiling.* The State must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(3) of this section.

(1) Name, address, telephone number, date of birth (or age), and gender of the patient.

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

(3) Pharmacist's comments relevant to the individual's drug therapy.

§ 456.709 Retrospective drug use review.

(a) *General.* The State plan must provide for a retrospective DUR program for ongoing periodic examination (no less frequently than quarterly) 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 Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. This program must be provided through the State's mechanized drug claims processing and information retrieval systems approved by HCFA (that is, the Medicaid Management Information System (MMIS)) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use existing systems provided that the results of the examination of drug claims as described in this section are integrated within their existing system.

(b) *Use of predetermined standards.* Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

(1) Therapeutic appropriateness, that is, drug prescribing and dispensing that is in conformity with the predetermined standards.

(2) Overutilization and underutilization, as defined in § 456.702.

(3) Appropriate use of generic products, that is, use of such products in conformity with State product selection laws.

(4) Therapeutic duplication as described in § 456.705(b)(1).

(5) Drug-disease contraindication as described in § 456.705(b)(2).

(6) Drug-drug interaction as described in § 456.705(b)(3).

(7) Incorrect drug dosage as described in § 456.705(b)(4).

(8) Incorrect duration of drug treatment as described in § 456.705(b)(5).

(9) Clinical abuse or misuse as described in § 456.705(b)(7).

§ 456.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by § 456.705(c) for use in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

§ 456.712 Annual report.

(a) *DUR Board report.* The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) *Medicaid agency report.* The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

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(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at § 456.703(f) and with the access to the predetermined standards requirement at § 456.703(g). After the first annual report, only changes must be reported.

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 456.714 DUR/surveillance and utilization review relationship.

The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455.

§ 456.716 DUR Board.

(a) *State DUR Board requirement and member qualifications.* Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

(1) Clinically appropriate prescribing of covered outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.

(3) Drug use review, evaluation, and intervention.

(4) Medical quality assurance.

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed by the State on whose DUR Board they are serving.

(c) *Medicaid agency/DUR Board relationship.* The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) *DUR Board activities.* The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) *Application of predetermined standards: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(iii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

(2) *Application of predetermined standards: Medicaid agency role.* The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.

(ii) If prospective DUR is conducted using an electronic claims management (ECM) system, apply software ed by the Board.

(iii) If prospective DUR is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(2)(A) of the Act.

(3) *Retrospective DUR: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(4) *Retrospective DUR: Medicaid agency role.* The Medicaid agency or its contractor should apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

(5) *Education program (including interventions): Board's activities.* The DUR Board should perform the following activities:

(i) Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.

(ii) Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy.

(iii) Periodically re-evaluate and, if necessary, modify the interventions.

(6) *Education program (including interventions): Medicaid agency's role.* The Medicaid agency or its contractor should perform the following activities.

(i) Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and interventions and furnish those reports to the Board.

(ii) Carry out the educational programs and interventions specified by the Board.

(e) *Funding for the Board.* FFP is available for expenses associated with the operation of the DUR Board in carrying out its responsibilities, and payment is made under procedures established in part 433 of this chapter as follows:

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(1) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are met, at the rate of 75 percent.

(2) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are not met, at the rate specified in § 456.719.

§ 456.719 Funding for DUR program.

FFP is available for sums that the Secretary determines are attributable to the Statewide adoption of a DUR program as described in this subpart, and payment is made under procedures established in part 433 of this chapter as follows:

(a) For funds expended by the State during calendar years 1991 through 1993, at the rate of 75 percent.

(b) For funds expended by the State after December 31, 1993, at the rate of 50 percent.

§ 456.722 Electronic claims management system.

(a) *Point-of-sale system.* Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The State determines who must participate in an ECM system and who may decline to do so. If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) *Functional requirements.* The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. The real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State to permit claims to be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and Medicaid agency.

(1) Eligibility verification, including identification of the following:

(i) Third-party payers.

(ii) Recipients in managed care programs.

(iii) Recipients and providers in restricted service programs (for example, lock-in and lock-out).

(iv) Properly enrolled providers.

(2) Claims data capture, including the following:

(i) Transfer of claims information from the pharmacy to the Medicaid agency or the Medicaid agency's contractor.

(ii) Identification of prescriber.

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

(c) *Additional requirements.* In order to receive FFP for its ECM system, the State must meet the following requirements:

(1) The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G–O of OMB circular A–102. The request for proposal (RFP) may be substituted for the advance planning and implementation documents otherwise required by part 433 of this chapter. 45 CFR 95.205, and 45 CFR part 307. A cost-benefit analysis must accompany the RFP. If in its advance planning document, a State establishes that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, procurement of network services and equipment (but not software modifications) must be competitively procured.

(2) States wishing to do prospective DUR as part of their ECM must do the following:

(i) Submit a cost benefit analysis showing the cost-effectiveness of such a system. A State's decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.

(ii) Establish a central State-wide electronic repository for capturing, storing, and updating data for all prescriptions dispensed and for providing access to such data by all authorized participants.

(iii) Design the system to access data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in § 456.705.

(3) ECM is considered a subsystem and must be fully integrated with the remainder of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

§ 456.725 Funding of ECM system.

(a) For funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management system (that is, the most cost-effective telecommunications network and automatic data processing services and equipment) that meets the requirements of § 456.722, FFP is available at a matching rate of 90 percent. After fiscal year 1992, ECM subsystems are funded at the standard applicable MMIS enhanced rates, subject to the requirements of part 433, subpart A of this chapter.

(b) FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: June 10, 1992.

William Toby,

Acting Administrator, Health Care Financing Administration.

Approved: June 25, 1992.

Louis W. Sullivan,

Secretary.

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EXECUTIVE DIRECTOR

TESTIMONY

Senate Bill 410

Senate Public Health & Welfare Committee

Tuesday, March 16, 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.

Senate P H & W
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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 program 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.

"(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

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-

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:

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.

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
VOLUME 14 NUMBER 4

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.

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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-related 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

REFERENCES

1. Goodwin DW, Guze SB. Psychiatric Diagnosis, 4th Ed., Oxford University Press, 1989.
2. Perry PJ, Alexander B, Liskow BI. Psychotropic Drug Handbook, 5th Ed., Harvey Whitney Books, 1988.
3. Alexander B. Antipsychotics: How strict the formulary? DICP 1988;22:324-6.
4. Weiner JM. Psychopharmacology in childhood disorders. Psych Clin N Amer 1984;7:831-43.

Philip J. Schneider, Pharm.D.

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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, dextrothyroxine, 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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KANSAS
D.U.R.
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:

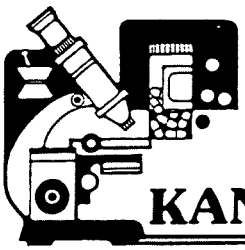
1. CONCOMITANT ADMINISTRATION OF KETOCONAZOLE (NIZORAL)
2. OVERDOSE, INCLUDING SINGLE DOSES AS LOW AS 360 MG
3. CONCOMITANT ADMINISTRATION OF ERYTHROMYCIN
4. SIGNIFICANT HEPATIC DYSFUNCTION

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.

L.U.R.



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J:COMM-LST 2/93

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

Senate Public Health and Welfare Committee
Testimony on Senate Bill 410

March 16, 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."

****

Madam Chairman and members of the committee, on behalf of Secretary 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 (performed by the pharmacist counseling the patient before dispensing the prescription) be in place by January 1, 1993. The Kansas Board of Pharmacy has a regulation requiring pharmacists to initiate oral patient counseling as a matter of routine; thus the Kansas Medicaid Program is in compliance with the prospective DUR requirements.

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 the sometimes 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. 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 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, as Kansas has done. The committee, or "Board" to use the federal term, is a working group of professional drug usage evaluators who have the knowledge and expertise to research the pertinent literature, and/or to request personal presentations, as needed.

Senate PH&W
Attachment #9
3-16-93

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. The Division of Medical Services, however, schedules a routine quarterly meeting with industry representatives to ask for their input, and to discuss issues of mutual interest.

Currently, the DUR Committee is not covered by the Kansas Open Meetings Act. It is not a state agency or committee but is a group of professionals who serve SRS under a contract between SRS and a private foundation, the Kansas Pharmacy Foundation.

The DUR Committee members recognize that they cannot be free of the marketing pressure of industry representatives outside of the meetings, but they have unanimously requested that their deliberations continue to be free of such pressures during DUR meetings. Their rationale, briefly stated, is that the federal Food and Drug Administration (FDA) approves drugs for marketing and sets the criteria for use. OBRA 90 and HCFA have set the criteria for evaluating such usage. The pharmaceutical representatives would contribute their sales and marketing information, when what the committee expects from invited experts is unbiased information.

It is not in the best interests of Kansas Medicaid recipients, the Kansas taxpayers, nor the SRS Division of Medical Services to allow the manufacturers to observe and influence the process of setting usage standards and criteria for their own and competitive products. Senate Bill 410 is unnecessary under federal statutes and would allow pharmaceutical sales and marketing personnel to exert inappropriate influence on the Drug Utilization Review process.

Robert L. Epps
Commissioner
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KANSAS CHAPTER

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March 15, 1993

The Honorable Sandy Praeger
State Senator
Capitol
Topeka, KS 66612

RE: S-410

Dear Senator Praeger:

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 into 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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Senate PH&W
attachment #10
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