Program Evaluation

KENTUCKY MEDICAID DRUG FILE AND PRIOR AUTHORIZATION SYSTEM

NOT ADOPTED BY PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE

PROGRAM REVIEW & INVESTIGATIONS COMMITTEE

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The Program Review and Investigations Committee is a 16-member bipartisan committee. According to KRS Chapter 6, the Committee has the power to review the operations of state agencies and programs, to determine whether funds are being spent for the purposes for which they were appropriated, to evaluate the efficiency of program operations and to evaluate the impact of state government reorganizations.

Under KRS Chapter 6, all state agencies are required to cooperate with the Committee by providing requested information and by permitting the opportunity to observe operations. The Committee also has the authority to subpoena witnesses and documents and to administer oaths. Agencies are obligated to correct operational problems identified by the Committee and must implement the Committee's recommended actions or propose suitable alternatives.

Requests for review may be made by any official of the executive, judicial or legislative branches of government. Final determination of research topics, scope, methodology and recommendations is made by majority vote of the Committee. Final reports, although based upon staff research and proposals, represent the official opinion of a majority of the Committee membership. Final reports are issued after public deliberations involving agency responses and public input.

T R A N S M I T T A L M E M O R A N D U M

TO: Governor, General Assembly, Cabinet for Health Services, and interested parties

FROM: Sen. Joey Pendleton, Chair
Rep. Jack Coleman, Co-Chair

DATE: December 12, 1997

RE: Committee Report -- Medicaid Drug File and Prior Authorization System

Attached is the final adopted report and recommendation of a study of Kentucky's Prior Authorization (PA) and formulary system. The Division of Clinic and Provider Services within the Department for Medicaid Services supervises this component of Medicaid. DMS also contracts with the UK College of Pharmacy for services related to formulary (drug file) and PA Management, and also with its fiscal agent, UNISYS.

The Medicaid "formulary" consists principally of two lists: a restricted PA list and a Non-PA list (the "formulary" or Outpatient Drug List). The combined lists contain over 100,000 National Drug Codes, about 30,000 on the PA list and about 70,000 on the Non-PA Drug List. In order to obtain a PA List drug, a patient, provider, and pharmacist must request Prior Authorization (approval) from DMS (through its fiscal agent, UNISYS).

The stated purposes of PA and the formulary are to control costs and to provide access. These two goals compete with one another to some extent. Kentucky has a high rate of general access and use (19.5 prescriptions per year, vs an average in other states of 14 to 15). This results in a very high rate of expenditures ($512 per recipient, vs about $430 nationally).

Although general access (use) is high, individuals may experience delays due to the requirements of the Prior Authorization (PA) procedure. These delays can become significant when a critical drug is in question, or when a patient is made to experience the therapeutic failure of a first line, Non-PA List drug before gaining access to a more recent (perhaps more effective) PA List drug.

Kentucky pharmacists have mixed opinions about the PA process (and formulary system). Some observe that it has the effect of making almost all FDA-approved drugs available. Others focus on the "hassle" and delay of the process. The Kentucky Pharmacists Association recorded several specific concerns regarding the PA procedure, but was generally supportive of the recent efforts of the Drug Management Review Advisory Board, which makes recommendations to DMS regarding PA and the Drug File. Patient advocacy groups and drug manufacturers are opposed to Kentucky's PA and formulary system.

It is not likely that the PA/formulary system is accomplishing the purpose of cost control. Kentucky drug benefit use and expenditure statistics are among the highest in the nation. An analysis of the costs of running the program, and the research literature on restrictive formularies, suggests that savings attributable to the formulary/PA system are unlikely. Furthermore, several states with open formularies and no PA procedures have lower drug expenditure and use statistics than Kentucky.

Recently, several changes in direction have taken place. A 1996 evaluation by Coopers and Lybrand found Kentucky's PA procedure to be less efficient and effective than other states' procedures. Also in 1996, the Drug Management Review Advisory Board (DMRAB) was created, with responsibilities for the Formulary, Disease Management, Drug Use Review, and Prior Authorization. DMS contracted with the UK College of pharmacy to have it manage DMRAB meetings and to do drug reviews and perform other services related to the drug benefit program.

When drugs are FDA-approved they are automatically placed on the PA List. The process by which these drugs are reviewed and recommended for inclusion on the open Outpatient Drug List has been slow and somewhat arbitrary. Recently, the process has also become politicized. Efforts are now being made to make the review and recommendation process more responsive and rational.

Finally, there are a number of new directions being taken to control costs and provide quality drug therapy. Managed care is one. The use of step-care, drug use protocols (rational drug therapy), drug use review, and other methods of cost control are also under consideration. The significance and pace of these events requires aggressive policy direction and clear statements of purpose, goals and targets for results. This study recommends that DMS undertake a thorough review to determine why utilization and costs are high, what goals and targets are to be addressed and what strategies will produce the most effective results.

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ACRONYMS AND TERMS

BMN	Brand Medically Necessary
C & L	Coopers and Lybrand
DFAB	Drug Formulary Advisory Board
DM	Disease Management (or Drug Management)
DMRAB	Drug Management Review Advisory Board
DMS	Department for Medicaid Services
DUR	Drug Utilization/Use Review
DURAB	Drug Use Review Advisory Board
EDS	Electronic Data Systems
EPSDT	Early and Periodic, Screening, Diagnosis, and Treatment
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HMO	Health Maintenance Organization
MCO	Managed Care Organization
MMIS	Medicaid Management Information System
NDC	National Drug Code
NPC	National Pharmaceutical Council
NSAIDS	Nonsteroidal Anti-Inflammatory Drugs
OBRA	Omnibus Budget Reconciliation Act
OTC	Over-the-Counter (Drug)
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PhRMA	Pharmaceutical Research and Manufacturers Association
POS	Point-of-Service (Sale)
SLC	Southern Legislative Conference
UK	University of Kentucky

CHAPTER I

INTRODUCTION

The Cabinet for Health Services (CHS) administers the Kentucky Medicaid Assistance Program (Medicaid). Kentucky Medicaid has chosen, as have all state Medicaid programs, to offer a pharmaceutical benefit program. The pharmacy benefit program is supervised by the Department for Medicaid Services' Division of Clinic and Provider Services.

In Kentucky, the drugs which are available to Medicaid recipients are listed, by their National Drug Code Number (NDC), on two lists:

- The Medicaid Outpatient Drug List (now called the "Non-PA Drug File")
- The Prior Authorization (PA) List (called the PA Drug File)

These (combined) files/lists are called the Medicaid Drug File. The general term for such a group of lists (especially the Outpatient or Non-PA Drug list), is "formulary". A related term is "prior authorization" (PA), which is a procedure through which a Medicaid recipient can gain access to a restricted, non-formulary drug by seeking permission (prior approval or authorization) to obtain it through the Medicaid (reimbursement) program.

SCOPE OF STUDY

This study focuses on the extent to which the Medicaid formulary and PA procedure provide access to drug therapy and control drug expenditures. Comprehensive comparative data for the years 1988 to 1995 are available and the report focuses on these years. The study does not address issues related to prescription drug ingredient costs, reimbursements, dispensing fees, drug rebates or rebate agreements, drug use or abuse, fraud, or cost control methods apart from the Medicaid PA and formulary process.

METHODOLOGY

Program Review staff interviewed officials and employees of the Department for Medicaid Services (DMS), the DMS Division of Clinic and Provider Services, and the fiscal agent (UNISYS). Interviews were also conducted with selected Medicaid pharmacy benefit officials (all pharmacists) in several selected states. Program Review staff interviewed and attempted to obtain written position statements from individual providers, provider organizations, patient advocacy organizations, and drug manufacturers.

Staff compared state and national drug expenditure trends and PA/formulary program profiles of Kentucky with those of the 16 Southern Legislative Conference (SLC) states and with a selected national cross-section of 12 other states. This analysis relied heavily on HCFA form 2082 report data, especially HCFA statistical data reported in the Comparative Data Report on Medicaid, produced by the SLC, and the 1996 edition of Pharmaceutical Benefits Under State Medical Assistance Programs, produced by the Lewin Group and published by the National Pharmaceutical Council (NPC).

The study report also reflects an analysis of DMS documents and reports, UNISYS reports, and the transcripts and minutes of many formulary, prior authorization,

and drug utilization advisory committee meetings. Finally, staff did an extensive review of the research literature on prior authorization and formularies as they affect cost, access and treatment (bibliography found in Appendix G).

OVERVIEW

Chapter 2 provides definitions and describes the development of the Medicaid formulary and PA procedure from their creations (respectively) in 1961 and 1976. Definitions of the major terms associated with formulary and PA processes are discussed, along with a chronology of the major statutory events and recent developments which define the current system. Chapter 3 evaluates the effectiveness of current PA and Medicaid formulary management (DMS and contractors) in accomplishing its stated purpose of providing access to drug therapies. Chapter 4 addresses the effectiveness of the PA/formulary system in terms of its stated purpose to control costs. In this regard, some of the policies and circumstances which limit the effectiveness of the formulary/PA process are discussed. Chapter 5 evaluates the efficiency and responsiveness of the formulary (drug file) program organization, and its related PA procedures. Finally, the report discusses other PA procedures and methods of cost control; for example, rational drug therapy and managed care.

CHAPTER II

BACKGROUND

Kentucky is one of 43 states which use some form of drug prior authorization (PA) procedure to control Medicaid drug expenditures, access, and utilization, but one of only nine states using a PA procedure in conjunction with a "closed formulary". A "formulary" is a listing of drugs which are "covered" and which may be prescribed for the patients or recipients of a health provider or plan. Hospitals use formularies to control and monitor the use of the drugs they provide to patients. Insurers and health maintenance organizations maintain drug formularies to control drug expenditures by listing, requiring the use of some drugs, and denying payment for others. Formularies may be classified as "open", meaning generally that FDA approved drugs will be paid for and provided, whether they are "on the formulary" or not. Alternatively, formularies may be restricted or "closed", meaning that drugs which are not specifically listed on the formulary are not "covered" and will not be paid for by the provider/insurer.

A Drug "prior authorization" (PA) procedure is often used to support (enforce) a formulary and also to authorize payment (override denial) for drugs or drug classes which are not listed "on the formulary". Thus, the purposes of formularies and prior authorization are very closely related.

System's Purpose is to Provide Access and Control Costs

A specific mission statement for Kentucky's restricted drug list was not available from DMS. However, several references to the purposes of the drug lists and the PA procedure exist. In essence, the purpose of the restricted drug list is control. In order to ensure that control does not adversely affect treatment, prior authorization permits access. However, the greater the access the less likely the financial savings. The current purposes set out by the Prior Authorization subcommittee show a movement away from the original mission (providing access) toward control.

According to the DMS Medicaid Pharmacy Manual, the purpose of the PA procedure is:

> to provide the Department for Medicaid Services (DMS) recipients with access to certain legend drugs not normally covered on the DMS Outpatient Drug List, ...

On the other hand, according to an official responsible for its supervision, the purpose of the Medicaid formulary and PA system is also "to exercise some form of control". The 1996 Administrative Order creating the Drug Management Review Advisory Board (DMRAB) defined its purpose as advising DMS ". . . regarding out-patient drug coverage and the delivery of quality care in the most cost effective manner possible . . . giving consideration to the therapeutic equivalence and cost of drugs . . . ."

Finally, the DMRAB Prior Authorization Subcommittee no longer identifies access as one of its purposes. At its May 12, 1996 meeting the PA subcommittee stated that PA is a means to:

- Control cost
- Minimize polypharmacy

- Minimize fraud and abuse
- Identify opportunities for provider education

Restricted Drugs Require Prior Authorization

Kentucky's Medicaid drug benefit program maintains a restricted ("closed") drug formulary (called the Outpatient Drug List), in combination with a prior authorization list (and procedure), which is used principally to override and approve the use of prescribed drugs which are not listed on the Medicaid Outpatient Drug List. The combined PA Drug List and Outpatient Drug List constitute the "Medicaid Drug File". The term "formulary" is not used (officially) by DMS. However, the Outpatient Drug List is often referred to as the "formulary," or "the list," or the drugs which are "on the card". Other terms currently in use are "restricted list" (PA) and "unrestricted list" (Non-PA). The most recent official DMS terms in use today are Non-PA Drug File (NPADF) and PA Drug File (PADF).

Medicaid payment for a PA List drug requires that a Medicaid recipient's provider and/or pharmacist obtain prior approval from the Department of Medicaid Services' fiscal agent (currently UNISYS). A request for prior authorization (PA) for a PA-List drug must be initiated by either a prescriber (physician) or a pharmacist. PA requests are initiated evenly between the two groups. However, physician PA requests are generally done by their nurses or office staff. The information required is the same, regardless of who initiates a request. Appendix A contains a copy of the "Prior Authorization/Authorization to Bill" form and an outline of the procedures for a request. This form may be mailed or faxed. As a third option, the information required by the form may be provided verbally by telephone. Exhibit 2.1 shows the essential information required. Generally, both the physician and pharmacist must be involved. Physicians prescribe the drug but tend to be uninformed about the restricted drug list. Pharmacists

are knowledgeable about the restricted drug list but are not routinely provided with the required diagnosis information on the PA form or prescription.

EXHIBIT 2.1

MAP 122 PA Request Form Information

The Medicaid recipient's name and Medicaid ID number
The prescriber's license number, name, and telephone
The drug name and National Drug Code (NDC) number
The drug's strength and quantity
The beginning and ending date of the prescription
The diagnosis and prognosis
Other drugs tried
Prescription directions and length of treatment
The pharmacy provider's number, name and telephone

Source: DMS MAP 122

Restricted Drug List Contains Over 30,000 Items, Administration Complex

Kentucky's Medicaid formulary has grown substantially. When first established in 1965, based on the 1961 Kerr-Mills Kentucky Medical Care Program, the formulary fit on a 3 by 5 inch card. Today's formulary (drug file) has 100,000 line items (drug codes) and is over 1,000 pages long.

In 1976, a prior authorization (PA) procedure was established to provide access to drugs which were not available through the formulary list. Today, this PA list has over 30,000 line items. The list is based on National Drug Codes; therefore, one drug may be listed multiple times to reflect different potency strengths and forms (pills, liquids). Authorization is specific to strength and form. Any change in strength or form requires an updated authorization.

Prior to 1990, Kentucky placed every new FDA-approved drug automatically on the PA-List. Kentucky used this approach until passage of the federal Omnibus Budget Reconciliation Act (OBRA) of 1990, which required that all drugs be placed on the open

formulary for at least 6 months. OBRA 1993 removed this requirement and Kentucky was one of only a few states to revert to its previous closed formulary and PA approach.

There have been several other recent developments, including the implementation of a Medicaid managed care system, contracting out the drug review process to the University of Kentucky, and a move toward using treatment protocols as a guide to prescribing drugs. These developments and a chronology of events from 1961 to the present are displayed in Exhibit 2.2 below.

EXHIBIT 2.2

History Of PA/Formulary System In Kentucky

1961	Drug list first established; fit on 3X5 card
1965	Medicaid program established, Drug List expanded
1976	Prior Authorization procedure established
1981	500 drugs removed from list, primarily over-the-counter; some legend drugs added
1990	OBRA 90; Federal government requires all new drugs be unrestricted for six months in exchange for rebate program by manufacturers
1992	Kentucky Drug Formulary Advisory Board (DFAB) created to determine drug list placement. Drug Use Advisory Board (DURAB) created in compliance with OBRA 90
1993	OBRA 93; Kentucky opts to use pre-OBRA 90 method of restricting all new drugs upon release by placing them on PA List
1995	Medicaid waiver to create managed care districts; effects on PA/Formulary processes and drug utilization are unknown
1996	DFAB & DURAB consolidated into Drug Management Review Advisory Board (DMRAB) UNISYS replaces EDS as fiscal agent Contract with UK College of Pharmacy to provide services related to formulary decisions, PA processes, drug utilization, and disease management
1997	Four DMRAB Subcommittees established: Drug File (Formulary), Prior Authorization (PA), Disease Management (DM), and Drug Use Review (DUR)

CHAPTER III

PROGRAM EFFECTIVENESS - PROVIDING ACCESS

To control drug program expenditures Kentucky's formulary and PA procedures are designed to restrict access to certain "second line", PA List drugs unless (or until) medical necessity has been demonstrated. Generally, all drugs go on the PA list immediately upon Food and Drug Administration approval. "Necessity" is defined in the DMS Pharmacy Manual as the provision of a PA List drug in order "to make an otherwise inevitable hospitalization or higher level of care unnecessary". Demonstration of necessity takes the form of provider diagnosis and argumentation/justification of medical necessity; for example, documentation of the "ineffectiveness" (therapeutic failure) of an Outpatient Drug List drug.

Advocates of restrictive formularies and aggressive PA procedures argue that, although access to specific medications may be delayed or denied, access to medically necessary (or therapeutically equivalent) drug therapy is not. Pharmacists contacted for this study did not indicate that general access is a significant problem. However, many did note that there were individual cases of delay and drug therapy treatment problems. Patient advocacy groups and drug manufacturers are opposed to Kentucky's current PA procedure and formulary. General (overall) access does not seem to be a problem, based upon Kentucky's high drug benefit expenditures, prescriptions per recipient, and 95-98% prior authorization approval rate.

PA and DMS Policies Promote Prescription Drug Use

Kentucky has a very high rate of per recipient drug use and correspondingly higher than average expenditures for its drug benefit program. In Kentucky, nearly every FDA-approved drug with a manufacturer's rebate agreement is made available to Medicaid recipients, either through the Outpatient Drug List or by the Prior Authorization procedure. DMS officials contend that the PA process promotes access. The following statistics seem to support DMS contentions.

- Annual volume of PA requests and approvals is increasing (from 153,311 in 1993 to 400,000 in 1997).

- Ninety-five percent (95%) to ninety-eight percent (98%) of PA requests are approved.

- The annual number of prescriptions dispensed per Medicaid drug recipient in Kentucky (19.5) is the highest in the Southeast.

- The portion of Kentucky Medicaid vendor payments devoted to drugs (12.9%) is the highest in the nation.

Kentucky's long term care (LTC) Medicaid patients are given blanket PA approval for each LTC resident's medications. Medicaid officials stated to Program Review staff that this exemption was given because LTC officials and advocates effectively argued that these patients, because of their condition, could not be exposed to the delays in access occasioned by the PA approval request process.

Kentucky's approach to balancing cost savings and access tends to favor access over more direct cost saving methods. Drug co-payment requirements have been used in thirty states. These drug co-payment requirements range from $.50 to $1.00 for generic drugs/prescriptions, up to $3.00 for brand name drugs. Of the 30 states, 26 have lower

drug expenditures than Kentucky. Another approach to cost control is to limit monthly per-person prescriptions. Forty-five (45) states record some form of prescription limitation. In most cases these limitations are no more restrictive than Kentucky's limitation of "five refills per six months". However, some states limit recipients to as few as three Rx's per month, and these states have correspondingly low per-recipient drug costs. In some states a PA approval process is in place to override these limitations, in cases of medical necessity. However, one state Medicaid pharmacy consultant observed to Program Review staff that some Medicaid recipients in her state "go without their meds" because their providers don't use the PA process to override the state's prescription limitation.

Prior Authorization Procedures Can Result in Denial or Delay

Although a high volume of drug benefits and general access are provided, specific and individual problems with access are present in the Medicaid program. In an individual's case, the access issue is one of quality and timeliness, rather than quantity. Often the issue is not one of access "denied" but access "delayed". Perhaps the most frequent delays occur at night and on weekends. The PA office of UNISYS is open Monday to Friday 8:00 a.m. to 6:00 p.m. Although there is a federal requirement to respond to PA requests within 24 hours on weekdays and 72 hours on weekends, delays can be slightly longer and weekends can pose significant problems. Several pharmacists remarked about the "hassle"" and delay involved. As one pharmacist in the survey stated:

> On weekends and holidays the treatment can be delayed unless the pharmacist is willing to advance a 1 to 2 day supply of medication to the patient at the risk of not getting the drug approved in the Prior Authorization procedures.

Individual Medicaid recipients are subjected to an element of chance regarding the extent to which they and their providers (physician and pharmacist) are willing or able to "go through the hassle" of obtaining an approval for a PA list drug. As one pharmacist stated to Program Review staff:

> In our store if an important drug is involved we usually loan the patient medications if we cannot get an immediate pre-authorization. I know of stores in the area, however, that tell the patient it may take a week and send them away without.

There are five criteria listed in the Medicaid Pharmacy Manual which must be met in order to receive a PA approval for a legend drug. Of these five criteria, two (3 and 5) affect individual drug therapy access most directly:

> (3) The requested drug shall be used in accordance with standards and indications, and related conditions, approved by the Food and Drug Administration (FDA) or documentation of effectiveness as listed in official compendia.
>
> (5) Drugs on the formulary shall be tried, when appropriate, with documentation of ineffectiveness prior to prior authorization.

Criteria 3 prohibits use (access) to drugs that are going to be used for "off-label" indications. FDA approvals for new, non-pediatric drugs do not carry indications for children under 18. Criteria five requires that "documentation of ineffectiveness" shall be provided. This means that an open formulary first-line drug must be tried first and the patient must then experience a "therapeutic failure" which may result in additional treatment costs or postponed treatment effect.

EXAMPLE:

The anti-psychotic drug, Zyprexa, provides an example of how PA criteria 3 and 5 affect the PA process. Zyprexa is an anti-psychotic used in the treatment of schizophrenia. Until October 1997, it was available only through the PA process (list). Many "first break" episodes of schizophrenia occur in the teenage years and a PA approval for Zyprexa would not be granted for a "first break" 17-year old. This person might be a candidate for Risperdal, which is on the Outpatient Drug List (open formulary). After Risperdal's FDA approval, it took about two years to move it from the Kentucky PA list to the Outpatient Drug List. There are at least two new FDA approvals for anti-psychotic medications on the horizon. The controversies and other struggles that have surrounded getting Risperdal (and currently, Zyprexa) moved from the PA list to the unrestricted formulary (Outpatient Drug List) may be repeated with these new drugs in the near future.

Zyprexa also provides an example of the way in which Kentucky's 5th PA criterion (documentation of ineffectiveness) can limit access. Therapeutic failure in the case of allergic rhinitus (allergy) may range from relatively slight to major annoyance. In the case of schizophrenia, the side effects, and the personal, medical, and social costs can be very substantial. In such cases of therapeutic failure, medication delayed is tantamount to medication denied. Even in the case of allergies, a significant delay in effective medication can lead to complications and lost productivity.

In spite of the above restrictions, 97% of PA requests for Zyprexa have been approved.

There are at least three other policies/procedures which occasion delays in access; what is generally referred to as the "hassle" of PA. First, because a PA approval is granted and recorded for a specific National Drug Code (NDC) number, any change in dosage strength or dosage form will carry a different NDC number and thus require an updated (new) PA approval. During treatment (especially in the early weeks) dosages are changed frequently, which can present both an immediate and a continuing problem for prescriber and patient. Each PA is also approved only for a specified pharmacy. Therefore, when a patient moves from one community to another, the new pharmacy must contact the old pharmacy to have it end its PA. Pharmacists report that this can cause some delay and confusion. Finally,

LTC patients who have received a waiver of PA requirements for their drug therapies must seek new PA approval for these same drugs when they are released from LTC.

**Pharmacists' Views of PA Vary;
Patient Advocates and
Manufacturers Oppose**

Program Review staff surveyed a cross-section of pharmacists to determine their views regarding the effect of the Formulary/PA system on access and patient treatment. Their views were mixed. Several observed that Kentucky's formulary/PA system, in general, provides access and adequate drug therapy. Others observed serious individual problems with access. Representative statements reflecting both views are displayed in Exhibit 3.1 below:

EXHIBIT 3.1

Pharmacist Views of Medicaid PA and Formulary

All recipients can receive drug therapy paid for by the program as long as the drugs prescribed are for an appropriate FDA indication. That is more than most insurance companies provide.
Most PA's can be taken care of in one day, so it doesn't impact the patient.
The formulary is broader in scope than many managed care programs and the PA process enables the physician/pharmacist to provide additional therapy if necessary.
The KMAP formulary works better than some of the managed care formularies I have to deal with.
The current process definitely has a negative impact on patient treatment. First, the delay means the patient cannot get the medication immediately, delaying his or her treatment, often for days. Second, because of the difficulty involved, many doctors and pharmacists become frustrated with the process, which inevitably makes them less likely to prescribe or dispense a medication requiring prior authorization. Third, the patient can become frustrated and give up on receiving the medication, which means he or she never receives the prescribed drug.
With release of new, expensive drugs a pharmacy cannot afford to give out a temporary supply of medications with the hope that they will get them prior authorized at a later day (regarding after hours and weekend requests).
Changes in PA/formulary sometimes interfere with patient care due to delays (when prescribers/pharmacists are not informed of changes).
Sometimes it is difficult to "get through" to PA operators at UNISYS; the problem is not so much one of access denial, but timeliness and delay.

The Kentucky Pharmacists Association (KPhA) recorded several significant concerns with PA/formulary processes; primarily the focus on pharmaceutical costs in isolation from other factors, and a belief that the present system does not deny drugs, but causes delays that may not be in the patient's best interest. However, it was generally supportive of the work of the Drug Management Review Advisory Board (DMRAB). The complete KPhA position statement is found in Appendix B.

The interests of advocacy groups and drug manufacturers regarding unrestricted access are similar. Such advocacy groups as the Mental Health Association of Kentucky (and Bluegrass Alliance for the Mentally Ill), Prevent Blindness America (Kentucky

Division), and the American Diabetes Association have recorded with Program Review their concerns regarding the formulary and PA procedure, and their desire for unrestricted access to drugs affecting client populations. Similarly, the Pharmaceutical Research and Manufacturers Association (PhRMA) has recorded its opposition to the PA system in a position statement provided in Appendix C.

Exhibit 3.2, below, displays the reasons given for opposition to the current formulary and PA procedure by PhRMA and advocacy groups.

EXHIBIT 3.2

Reasons Given for Opposition to Formulary/PA Procedures

Prior authorization and restrictive formularies drive costs up, not down
Restriction in access reduces the quality of care
Prescription drug benefits are a very small segment of Medicaid costs to target
Patients have very individual responses to drugs, even when the drugs in question may be therapeutically equivalent; thus all drugs in a class should be equally available
New drugs have a limited patent life and limiting initial access to the market permanently reduces profit and the recoupment of R & D costs; thus jeopardizing R & D for new drugs generally

CHAPTER IV

PROGRAM EFFECTIVENESS - CONTROLLING EXPENDITURES

Many different approaches, such as co-payments, prescription limits, and generic brand use, are used by other states to help control costs. Kentucky uses a restrictive drug list approach. With this approach, the claim is, savings result from promoting the use of older forms of drugs, which tend to cost less than newly released drugs. However, major research studies conclude that restrictive formulary approaches do not contain health care (and Medicaid) costs, because of "cost shifting: and "service substitution" resulting from the use of (need for) higher treatment modalities (e.g., physician visits, emergency room treatment, hospitalization). There have been no studies which demonstrate the cost savings or cost-effectiveness of Kentucky's PA and formulary system, or restrictive formularies in general.

Compared with other states, Kentucky's drug benefit use and expenditures are among the highest in the county. Additionally, the rate of increase in these costs is greater than for other states. Several states with open formularies and no PA procedures have lower drug benefit expenditures than Kentucky. Factors other than the effectiveness of the formulary/PA process may be driving costs.

Recipient Drug Expenditures and Use Are Highest in Region

The following Health Care Financing Administration (HCFA) statistics support a finding that Kentucky Medicaid drug expenditures per recipient, and the number of prescriptions per recipient, are higher than those of most comparable states and the national average.

- Kentucky's 1995 per-drug-recipient drug expenditure was $512, higher than all other (15) Southern Legislative Conference (SLC) states, and 8th highest in the nation, 28.7% higher than the SLC average, and 19.1% higher than the national average of $430 (Exhibit 4.1).

- In 1995, Kentucky issued 19.5 prescriptions per drug benefit recipient, highest of the 16 SLC states. The SLC average was 14.8. In other words, Kentucky issued 32% more prescriptions per recipient than the average SLC state.

- The average Kentucky Medicaid prescription price has increased 200% since 1988, but the average annual Medicaid drug expenditure per recipient has increased 251%.

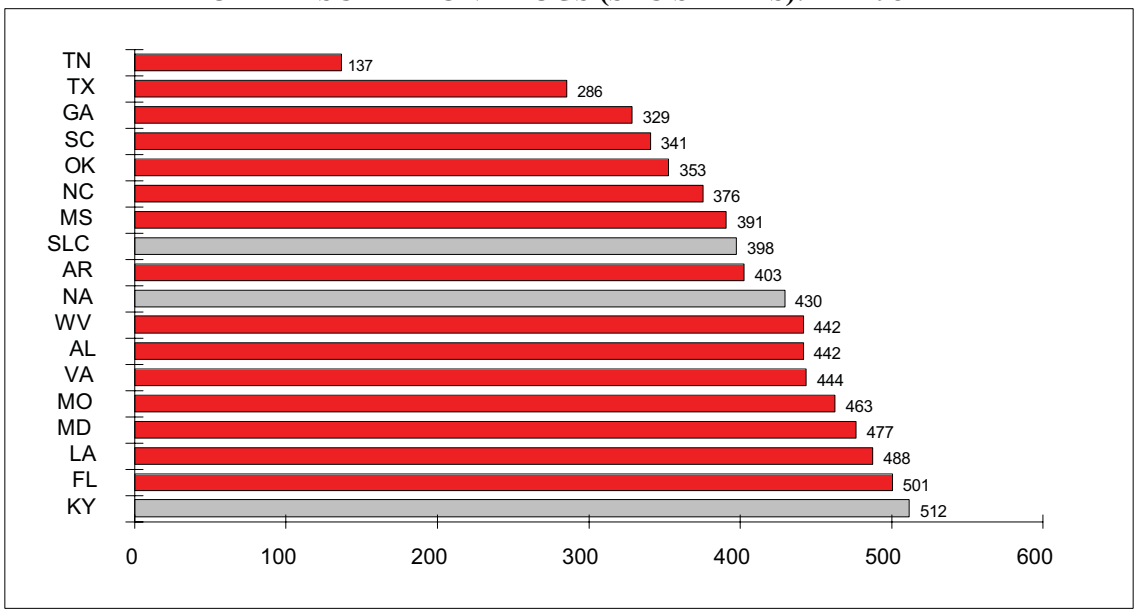
- Kentucky ranks 4th in growth among SLC states in per-recipient Medicaid drug costs between 1988 and 1995, but 15th (next to last) in growth of total Medicaid payments to recipients.

- Recent increases in drug payments per drug recipient have been dramatic, from $274 per recipient in 1991 to $512 in 1995, an 87% increase in four years, compared with a 61% increase nationally (Exhibit 4.2).

- Although Kentucky's 1988-95 average annual growth in total Medicaid payments per recipient was 10.3%, its average annual rate of growth in per-recipient drug expenditures was 19.6% (compared with only 9% for the SLC states).

EXHIBIT 4.1

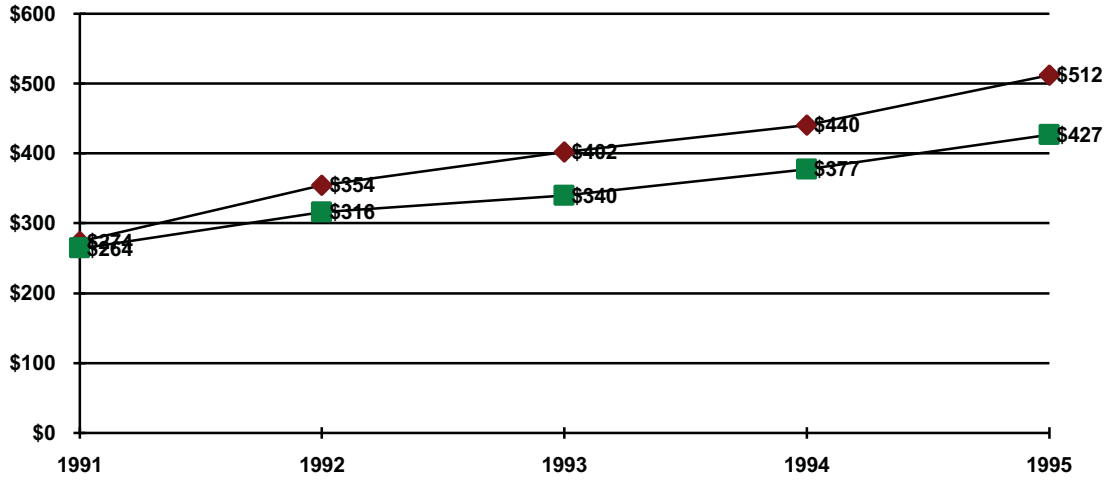
AVERAGE PAYMENT PER RECIPIENT FOR PRESCRIPTION DRUGS (SLC STATES): FFY 95



OURCE: HCFA 2082, as analyzed in Comparative Data Report on Medicaid, SLC, 1996.
Note: SLC = Southern Legislative Conference Average; NA = National Average

EXHIBIT 4.2

KENTUCKY AND NATIONAL AVERAGE DRUG PAYMENTS PER MEDICAID DRUG RECIPIENT, 1991 - 1995



SOURCE: The Lewin Group analysis of HHS Report HCFA-2082, in Pharmaceutical Benefits under Medical Assistance Programs, 1996, National Pharmaceutical Council.
Note: National Average exclusive of D.C. and Kentucky

Overall Drug Costs and Rates of Increase Among Highest in Nation

Kentucky's drug benefit expenditures and rates of benefit cost increases are, essentially, the highest in the country. Drugs account for 13% of our Medicaid expenditures; the highest percentage in the nation. Although our drug recipients have increased 7% per year, drug payments have increased 26% per year. Other data indicate that:

- 12.9% of the total 1995 Kentucky Medicaid vendor payments were for drugs, the highest percentage in the nation. The 1995 national average is 8.2% and has remained at about this level for the last few years. Kentucky's percentage has been rising each year (from 10.5% in 1991 to 12.9% in 1995) (See Exhibit 4.4). This is a 23% increase for Kentucky, compared with a 10% increase nationally.

- Of Southern Legislative Conference (SLC) states reporting 1996 drug budget dollars, Kentucky's drug budget, as a percentage of its overall Medicaid budget, is 2nd highest, at 11.3%. This is 26.3% higher than the overall average percent of 1996 SLC state Medicaid budgets devoted to drugs (8.95%).

- The number of Kentucky drug recipients increased an average of only 7.4% per year (from 1988 - 1995) compared with the SLC state average of 9.2%. However, Kentucky drug payments during this period increased an average of 26.5% annually, compared with the SLC state average of 19%.

- The rate of annual cost increases (1988 - 1995) for drugs has been significantly greater than other for Medicaid services; e.g., twice the rate of physician service and hospital costs.

- Finally, during the period 1991-95 the number of drug recipients increased 21%. However, the portion of vendor payments paid for drugs increased 23%; payments per recipient increased 87%; the portion of the Medicaid budget devoted to drugs increased 105%; and total drug payments increased 126% (Exhibit 4.5).

A summary of some of the above per-recipient and benefit cost statistics is provided in Exhibit 4.3.

EXHIBIT 4.3

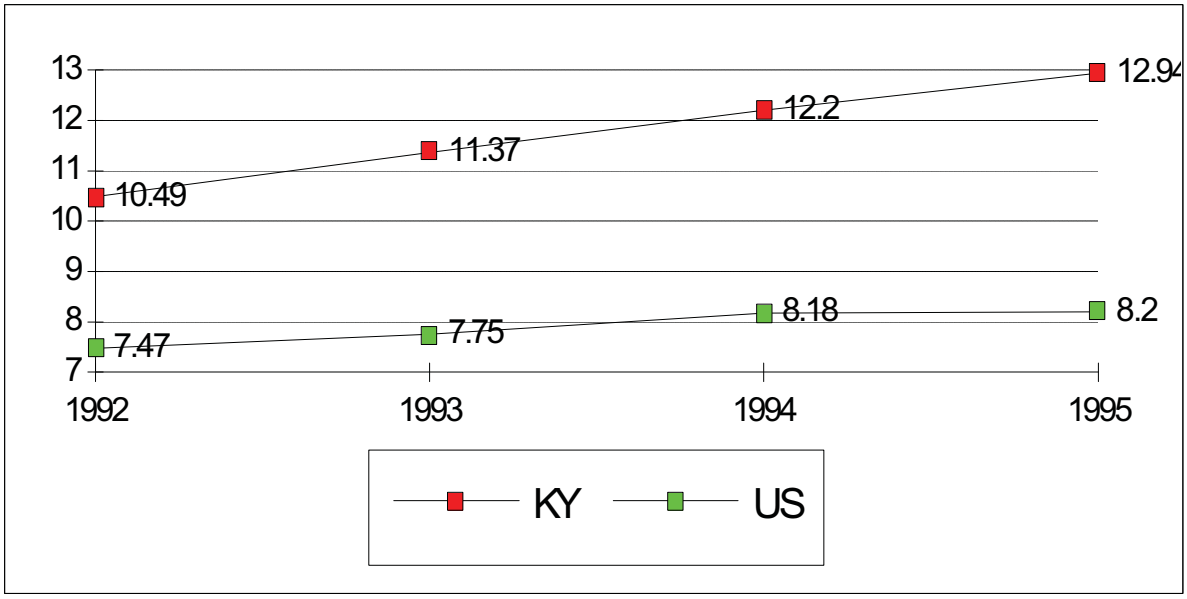
Kentucky Drug Expenditure Increases Compared to US and SLC Averages

PARAMETER	KY	US	SLC	% DIFFERENCE
% of 1996 Budget for Drugs	11.3%		8.95%	+ 26.3%
% of 1995 Vendor Payments for Drugs	12.9%	8.2%		+ 57.3%
1995 Per Recipient Drug Cost	$512	$430		+ 19.1%
Percentage Increase in per Recipient Drug Cost (1991-1995)	87%	61%		+ 42.6%
1995 Prescriptions per Recipient	19.5		14.8	+ 32.0%
Average Annual Per Recipient Drug Cost Percentage Increase 1988-95	19.6%		9.0%	+ 118.0%
Average Annual Drug Payment Increase 1988-95	26.5%		19.0%	+ 39.5%

SOURCE: NPC Pharmaceutical Benefits under Medicaid Assistance Programs, 1996, and Comparative Report on Medicaid, 1996, Southern Legislative Conference.

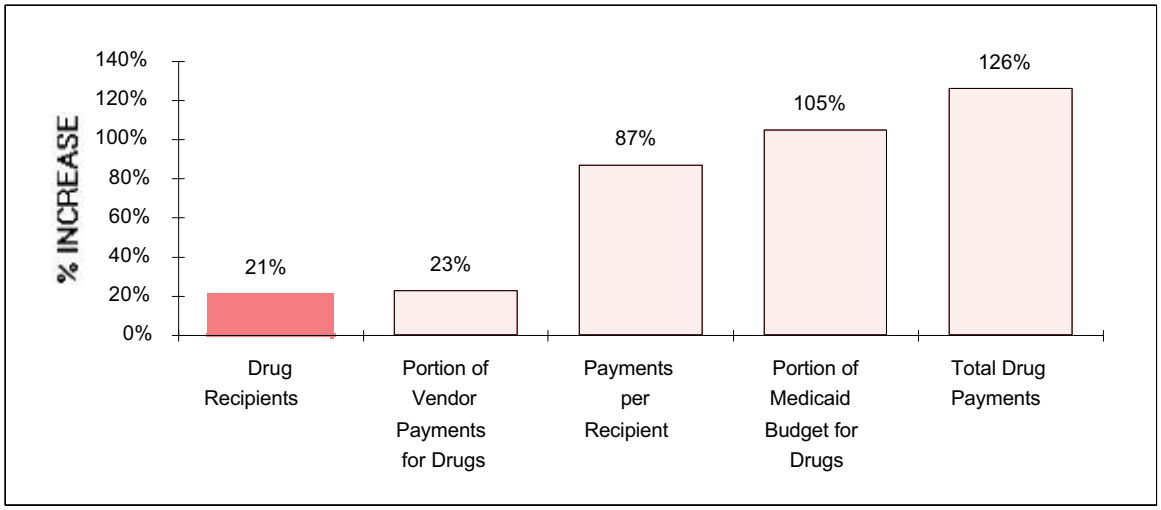
EXHIBIT 4.4

Percentage of Total Kentucky Medicaid Vendor Payments Paid for Prescription Drugs Compared with the Percentage Paid for Prescription Drugs Nationally, 1992 - 1995



SOURCE: The Lewin Group analysis of HHS Report HCFA-2082, in Pharmaceutical Benefits under Medical Assistance Programs, 1996, National Pharmaceutical Council.

EXHIBIT 4.5
The Percentage Increase in the Number Of Kentucky's Medicaid Drug Recipients Between 1991 and 1995, Compared with Corresponding Increases in Drug Costs



SOURCE: HCFA 2082 Reports 1991 - 1995.

Cost/effectiveness Undetermined, Savings Unlikely

Program Review determined in its Medicaid study of 1993 that the cost per PA in Kentucky was $8.48. However, this figure was based only on EDS/fiscal agent contract costs (and a PA volume of 153,311) and did not factor in the supervision/management costs of DMS, nor would it include recent and increasing DMS - UK contract costs, or any other costs associated with the PA/formulary process. Conservatively estimated, the actual per-PA cost must now approach $10, and 95% of (i.e., 19 of every 20) PA requests, at $10 per request, are approved. Therefore, it now must cost over $200 to deny a PA request. The average PA prescription drug cost is just over $31.46 (1995) and the average duration of a PA prescription is under 6 months. Therefore, this approach to PA can do no better than break even. Any program savings attributable to the PA procedure must come from restrictions on access to PA List drugs for which PA requests are never made. It is extremely difficult to determine how much is "saved" in this fashion.

Still, DMS and the proponents of restrictive formularies and PA procedures argue that the "sentinel effect" of denying or delaying immediate access to PA list drugs reduces costs. However, academic studies find that such restrictive formulary implementation often results in cost shifting to higher cost therapies, and "diagnosis shifting" toward (in conformity with) reimbursable drug therapies.

A few studies of Medicaid formulary restrictions have been done. One study done by D. Dranove (1989) looked at the results of easing restrictiveness on anti- infective therapy. Results showed insignificant cost increases, combined with improved quality of Medicaid care. A more significant study by W. J. Moore and R. J. Newman (1993) examined the totality of the Medicaid Program in the context of formulary restrictions. The study looked at states with formulary restrictions. The central finding of the study was:

> . . . a restricted formulary may reduce prescription drug expenditures by approximately 13 percent, on average. Because of service substitution, however, such a policy does not translate into reductions in total program expenditures. Savings in the drug budget appear to be completely offset by increased expenditures elsewhere in the system.

Two other recent studies relate directly to Medicaid. A 1991 study by S. B. Soumerai examined the effects of drug restrictions on New Hampshire nursing home admissions; looking particularly at the period of time in which a Medicaid restriction of 3 Rx's per month, per patient was in effect. This study found that:

> Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may increase Medicaid costs.

A second Soumerai study (1994) looked at the effects of pharmaceutical restrictions on patients with schizophrenia. This was a similar study of the New Hampshire 3-prescription cap requirement, compared with New Jersey's practice (no cap). The study reported that during the period of time when the (New Hampshire) cap was in effect, the increase in mental health services costs was seventeen times higher than the savings in drug costs. The study concluded that:

> Limits on coverage for the costs of prescription drugs can increase the use of acute mental health services among low-income patients with chronic mental illnesses and increase costs to the government even aside from the increases caused in pain and suffering on the part of patients.

The most comprehensive study of restrictive formulary effects on costs and patient outcomes was funded by the National Pharmaceutical Council and published by Susan Horn, Senior Scientist of the Institute for Clinical Outcomes Research, Salt Lake City. This was a study of six Health Maintenance Organizations (HMO's) and an assessment of services and outcomes related to 12,997 patients and five (5) disease states. In the words of Horn:

> We found that when formularies were restricted, the use of health-care services ranged to up to twice as great as at the site with no formulary. Of the six HMOs studied, the one with no formulary almost always had the lowest expenditures on health-care services.

However, it should be noted that program results and academic research have found that limited, narrowly focused PA procedures which relate to disease/drug management, step care and rational drug therapy protocols that concentrate on a disease state and a drug class, can control drug costs (in the area in which they are focused).

States With Open Formularies and No PA Have Lower Expenditures

Would Kentucky Medicaid drug expenditures necessarily be higher without the current PA/Formulary system? One way to approach the question is to compare Kentucky drug expenditures with those of the seven states that use no PA process and have open formularies (and in one case, no formulary at all).

Exhibit 4.6 compares Kentucky drug benefit/expenditure statistics with those of the seven states which have an open formulary and no PA system. Although all but one of these states have higher average prescription costs (prices) than Kentucky:

- all of them spend a significantly smaller portion of their Medicaid budget for drugs than Kentucky;
- all of them (except one) spend less per drug recipient than Kentucky;
- all but one process fewer drugs per recipient annually than Kentucky;
- on all three of the above measures of expenditure and use, half of these no-PA/open formulary states are at, or below, the national average.

EXHIBIT 4.6

Comparison of Kentucky with States Having No Medicaid Prior Authorization Process, 1995

STATE	PA/FORMULARY STATUS	AVERAGE Rx COST	DRUG PAY PER RECIPIENT	PER CENT OF VENDOR PAYMENTS FOR DRUGS	# OF Rx PER RECIPIENT
KENTUCKY	(PA/Closed Formulary)	$25.00	$512	12.9%	19.5
CONNECTICUT	(No PA/No Formulary)	$33.00	$531	6.8%	13.6
DELAWARE	(No PA/Open Formulary)	$28.00	$378	6.6%	15.4
INDIANA	(No PA/Open Formulary)	NA	$438	10.0%	NA
LOUISIANA	(No PA/Open Formulary)	$26.00	$488	10.8%	18.8
NEW HAMPSHIRE	(No PA/Open Formulary)	$23.00	$461	7.2%	19.7
NORTH CAROLINA	(No PA/Open Formulary)	$27.00	$376	8.7%	13.1
WYOMING	(No PA/Open Formulary)	$28.00	$335	7.0%	11.9
AVERAGE	(not including Kentucky)	$27.50	$430*	8.2%**	15.5
KENTUCKY - (Percentage Above/Below Avg.)		-9.1%	+19.1%	+36.4%	+25.8%

SOURCE: NPC Pharmaceutical Benefits Under State Medical Assistance Programs 1996. (Lewin Group and Program Review analysis of HCFA-2082 data and Lewin Group state survey)

* $430 per drug recipient is also the national average

** 8.2% of vendor payments paid for drugs is also the national average.

Kentucky Drug Costs May Be Affected by Factors Other Than PA/Formulary

Kentucky's Medicaid program has unique characteristics and generous pharmacy benefit features. These, combined with an absence of cost control programs found in other states, result in increased drug use and expenditures which are not subject to, or controlled by, the PA/formulary process. DMS officials state that the effect of the Formulary/PA system on cost control must be understood and evaluated in the light of these unique factors, which may increase drug expenditures for Kentucky, but not other states. These include the blanket authorization for LTC patients, lack of co-payments,

higher dispensing fees, and the health of the people. While data suggest these factors are driving costs, the actual impact on expenditures is not known.

The PA/formulary process does not apply to LTC residents. Long-Term Care (LTC) residents receive a blanket prior authorization approval, and according to DMS/UNISYS reports, the 1997 average annual per recipient drug cost for LTC patients was $1,311.00 versus $433.00 for the ambulatory Medicaid drug recipient population. Additionally, the pharmacy payment dispensing fee is $5.75 for LTC resident drugs, versus $4.75 for outpatient drugs. Only seven other states have dispensing fees this high, and apparently none have a special fee for LTC prescriptions. LTC per recipient drug costs almost doubled between 1994 and 1996 and per recipient drug costs for LTC residents are currently three times that of outpatient recipients. Exhibit 4.7 below displays the dramatic growth of drug expenditures generally, and LTC drug expenditures in particular.

EXHIBIT 4.7

Outpatient and LTC Per Recipient Drug Costs, 1994 -1997

FY Year	Outpatient	% Change	LTC	% Change
1994	$245.16	-0-	$ 691.21	-0-
1995	$369.98	(+) 50.9%	$1,099.40	59.1%
1996	$362.64	(-) 2.0%	$1,117.56	1.7%
1997	$443.48	(+) 22.3%	$1,310.97	17.3%
Increase 1994 - 1997	$198.32	(+) 80.9%	$ 619.77	89.7%

Source: Data provided to Program Review by DMS/UNISYS

Kentucky has no drug co-payment requirements. A majority of states (including those with open formularies and no PA procedures) have their drug costs reduced by required recipient co-payments ranging between $.50 and $3.00 (for some drugs). Often a co-pay of $.50 is assessed for generic drugs and $2.00 for brand name. Kentucky also has less restrictive prescription limitations than several other states. Kentucky's only

prescription limitation is five re-fills in six months. Exhibit 4.8 below shows the prescribing limitations and co-payments in force in the seven states with open formularies and no prior authorization programs.

EXHIBIT 4.8

Prescription Limitations and Patient Cost Sharing in States with Open Formularies and No Prior Authorization Process

STATE	PRESCRIBING LIMITS	PATIENT CO-PAYMENT	PAYMENTS PER RECIPIENT
Connecticut	240 tablets or capsules per Rx	No	$531
Delaware	34-day supply or 100 unit doses per Rx	No	$378
Indiana	No limitations	$.50 - $3.00	$438
Louisiana	30-day supply or 100 unit doses per Rx 5 refills per Rx within 6 months	$.50 - $3.00	$488
New Hampshire	No Limitations	$.50 - $1.00	$461
North Carolina	6 Rx per month 100-day supply per Rx	$1.00	$376
Wyoming	3 Rx per month	$1.00	$335

Source: Lewin Group Survey and HCFA 2082 Report data reported in Pharmaceutical Benefits Under State Medical Assistance Programs, 1996 (NPC)

Kentucky has a higher proportion of "Permanently and Totally Disabled" Medicaid recipients than most states. This category of recipient uses a disproportionate share of prescription drug benefits. However, several southern states have an even higher percentage of disabled recipients than Kentucky, but lower per recipient drug use and expenditure (e.g., Mississippi, Georgia, Tennessee, Arkansas, South Carolina, and Alabama). Alabama's percentage of disabled Medicaid recipients (24.8%) is 37.8% higher than Kentucky (at 18%) but its 1995 per recipient drug cost ($442) is 15.8% lower than Kentucky's ($512).

The overall health and health-related behavior of Kentuckians is a more likely contributor to high Medicaid drug expenditures. Exhibit 4.9 displays some of the results of a Center for Disease Control survey related to Kentucky citizen perceptions about their health and health-related behaviors.

EXHIBIT 4.9

Affirmative Responses to Various Health-related Survey Questions: Kentucky and U. S. Comparison

Category	KY	US	Rank
Have Poor/Fair Health	21.1%	13.9%	3rd Highest
Number days sick during past month	4	3	Highest (tied with 4 other states)
Current Smoker	27.8%	22.2%	Highest
No Physical Leisure Activity Past Month	45.9%	29.8%	Highest
Don't Get Five Fruits/Vegetables Daily	82.7%	76.1%	3rd Highest

Source: Centers for Disease Control survey results reported in American Demographics, August 1997.

CHAPTER V

EFFICIENCY AND RESPONSIVENESS

Almost all states use a PA procedure, but few are like that of Kentucky. Kentucky's PA and formulary (drug file) system is unique, in terms of the size of its drug lists, the use of NDC numbers rather than drug names, the enormous volume of PA requests and approvals, and the cost and complexity of its management structures. PA request volume has increased over 150% during the past three years and a recent evaluation determined that Kentucky's PA procedure is less efficient and effective than those of other states. PA request procedures have become more responsive, but several inefficiencies remain.

The management structure in place to manage the formulary and its required drug reviews is growing in size, cost and complexity. Contracts with UK are growing in scope and cost. Although several new policy directions have been established, the old PA system is running (and growing) parallel with the new. The new Medicaid Managed Care system will have a significant, but undetermined impact on the Formulary/PA process.

Prior Authorization

The size and scope of Kentucky's PA procedure is greater than those of other states and PA requests and costs are increasing. A recent evaluation of the Kentucky PA

procedure determined that it is less efficient and effective then PA procedures in other states. The PA procedure has become more responsive recently, but several inefficiencies remain.

Kentucky PA Size and Scope Greater Than Those of Other States

Although 43 states have a PA procedure, the meaning and function of "prior authorization" is quite different among states. In Indiana, state PA approval will soon be required to obtain a brand drug for which a generic equivalent is available. Indiana's chief Medicaid pharmacist calls this a "scalpel" approach to PA, as opposed to a "sledgehammer" such as California's. Ohio has a "closed" formulary and a PA procedure that appears ("on paper") to look much like Kentucky's. However, the Medicaid pharmacist in Ohio makes most formulary decisions himself and most FDA-approved drugs are placed "on the formulary". Only in those cases where his decision to restrict a drug may cause repercussions does he use the formulary committee to sustain (or override) his decision.

At the other end of a continuum of PA definitions is California. California has a closed formulary and a highly elaborate PA procedure. PA approval may be obtained from a regional Medi-Cal consultant for covered items or services not included on the Medi-Cal List of Contract Drugs (including special circumstance overrides of multiple source drug reimbursement ceilings or minimum quantity/frequency of billing limitations). Authorization is only given for the lowest cost item or service that meets a patient's medical needs. On a case-by-case basis, the California Medicaid Program also restricts, through prior authorization requirements, the availability of prescription drugs to beneficiaries or prescribers who abuse benefits.

Program Review staff surveyed 10 states regarding their formulary and PA procedures. Exhibit 5.1 displays the current status (and definitions) of their formularies and PA systems. A survey of these states revealed that the term "PA" can refer to a "drug NDC by drug NDC" approach like Kentucky's, or something as simple as screening for a handful of drugs or drug classes (West Virginia), or special situations, such as requiring PA (for a Brand Medically Necessary) override of the required use of a generic drug (Indiana).

EXHIBIT 5.1

Formulary and PA Status: A Comparison of Kentucky with Ten Surveyed States

STATE	FORMULARY STATUS	PRIOR AUTHORIZATION (PA) STATUS	Per Recipient Drug Cost (1995)
KENTUCKY	Closed. All rebated products not on the outpatient drug list are covered by inclusion in the drug PA procedure	Has a PA procedure covering rebated products not on the outpatient drug list	$512
ARIZONA	No formulary	PA procedure which screens for drug classes and individual drugs	$30
CALIFORNIA	Closed	PA may be obtained for covered items/services not included on the List of Contract Drugs	$313
CONNECTICUT	Open	No PA procedure	$531
INDIANA	Open for legend drugs	No PA procedure	$421
NORTH CAROLINA	Open for legend drugs. Cosmetic and fertility drugs excluded	No PA procedure	$438
OHIO	Closed	PA is needed for certain individual drugs	$476
OKLAHOMA	Open	PA is required for certain classes of minor tranquilizers	$353

VIRGINIA	Open, with exclusions	PA procedure screening for some individual drugs	$444
WEST VIRGINIA	Open, with exclusions	PA procedure screening for drug classes and home health care	$442
WYOMING	Open, with exclusions	No PA procedure	$335

SOURCE: NPC Pharmaceutical Benefits Under State Medical Assistance Programs, 1996.

PA Request Volume, Staff and Expenditures Increasing

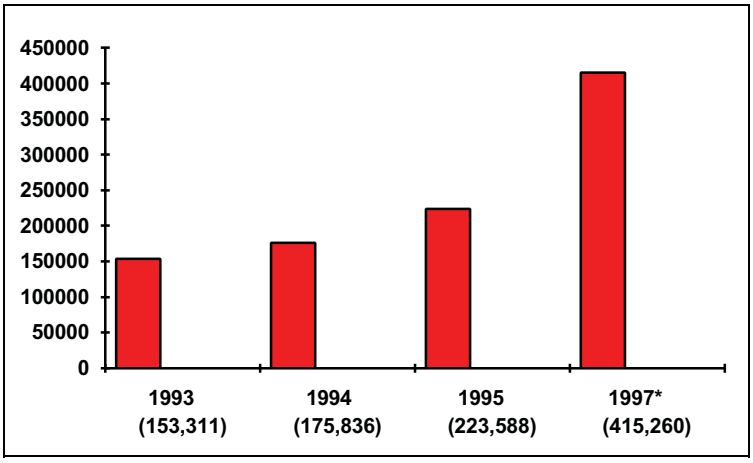
The volume of PA requests in Kentucky grew from 153,311 in 1993 to 223,588 in 1995 an increase of 46%. Currently, the annualized number of PA requests is 415,260, reflecting a 171% increase in PA volume in 4 years (See Exhibit 5.2) Similarly, the number of PA requests per thousand recipients has been rising, from 311 in 1993 to 375 in 1995. Exhibit 5.3 compares the per recipient volume of PA utilization in Kentucky with that of seven other states which use a PA procedure. Kentucky is the highest. As explained earlier in this report, each PA request costs about $10, and costs (paid to UNISYS) are based on claims volume. Therefore, as PA request volume approaches 400,000 annually, costs to DMS from the fiscal agent may approach $4,000,000 for the expense of telephone operators, equipment and processing. Actual cost is unknown at this point. When asked for PA expenditure or cost data, UNISYS and DMS indicated they were unable to break out or identify them as separate from other processing costs. Additionally, the salary costs for UNISYS PA personnel are regarded by UNISYS as proprietary, and undisclosed.

In order to meet the increase in PA requests, UNISYS has increased its staff to 10 full-time and 14 part-time drug PA procedure employees, including additional PA telephone operators (currently 10) and other PA staff. This is the second major increase in MMIS/fiscal agent PA employees this decade. In the early 1990's EDS increased the number of PA employees in order to meet growing PA request demand at that time. DMS

has indicated that only one person is assigned PA responsibilities. However, interviews with personnel in the Division of Clinic and Provider Services indicate that at least five people have some level of responsibility for PA and formulary list management.

EXHIBIT 5.2

Kentucky Medicaid PA Request Volume
1993 - 1997

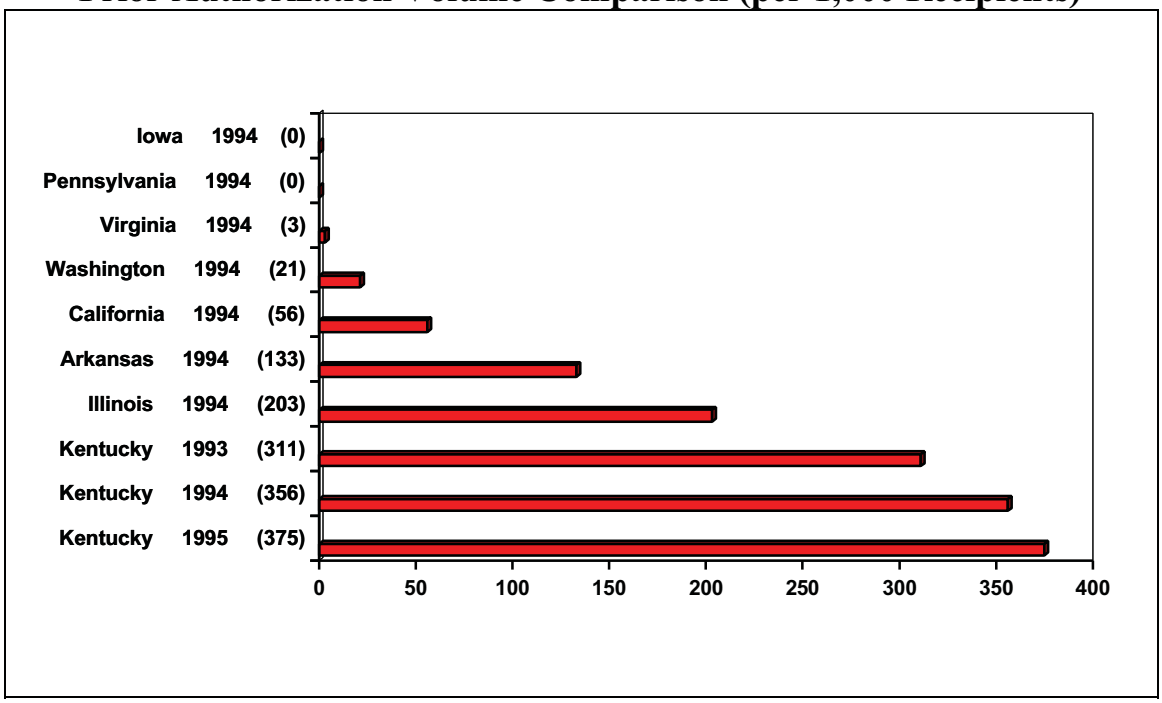


Source: Coopers and Lybrand Evaluation and UNISYS Report to Program Review.

* The 1997 figure is an estimate based on a DMS report (to Program Review) showing a volume of 207,630 PA requests made during the 6-month period 12/1/96 to 5/30/97.

EXHIBIT 5.3

Prior Authorization Volume Comparison (per 1,000 Recipients)



Source: Coopers and Lybrand data

Private Report Finds PA System Less Efficient/Effective

The central finding of a May 1996 Coopers and Lybrand (C & L) evaluation of the Kentucky Medicaid PA system conducted for PhRMA was:

> Compared to other similarly situated states with PA prescription drug programs, Kentucky's program does not appear as efficient or effective when measured on several basic performance indicators.

Regarding efficiency and effectiveness the Coopers and Lybrand evaluation found that:

- Administrative costs for the Kentucky PA program are three times higher than PA states (surveyed by C & L) and three times the cost per drug recipient;

- Kentucky PA request volume is more than twice that of surveyed states using PA systems, and it is increasing;

- The number of Kentucky drug NDC's requiring PA is 10 times the US average;

- The Kentucky PA approval rate is 13.4% higher than surveyed PA states;

- Kentucky PA requests per thousand recipients is more than 3.5 times that of surveyed PA states, and increasing;

- Drug costs per recipient are 32% higher in Kentucky than in surveyed PA states, and 9.1% lower than Kentucky in the surveyed states that don't have PA systems.

DMS officials are generally dismissive of the C & L report, stating that it "supported the position of the people who paid them to do it", that is, the Pharmaceutical Research and Manufacturers Association (PhRMA). Asked by Program Review staff if DMS had any specific responses to the recommendations that C & L made in the report, DMS officials stated that they had none (C & L recommendations are included as Appendix D). DMS officials recorded with Program Review staff the following specific concerns with Coopers and Lybrand and with its evaluation of the Kentucky Medicaid PA program:

- C & L did not address the effect on cost and use or the fact that Kentucky does not use other cost control programs that limit access (e.g., co-payments and prescription limitations). Also, the cost effect of the long-term care (LTC) blanket PA approval (and higher dispensing fees) was not addressed by the C & L report;

- Kentucky data used in the report may not be reliable because of the confusion surrounding the transition from EDS to UNISYS as the fiscal/MMIS agent (DMS expresses a general lack of confidence in UNISYS reports). Also, C & L did not use the EDS history tapes of PA and claims activity to identify cost locations and drug utilization, as they said they would;

- Finally, the term "prior authorization" refers to widely differing processes which do not lend themselves to easy or accurate comparisons. For example, because Kentucky uses NDC numbers rather than drug names, the size of the lists and the number of PA requests that are (i.e., must be) made is larger than other states.

PA Procedures Are More Responsive, but Inefficiencies Remain

Although responsiveness to PA requests has improved, a number of inefficiencies have been brought to the attention of Program Review staff. Below are observed inefficiencies discussed at the latest meetings of the PA subcommittee and full DMRAB in September, 1997. These include the complexity of the request procedure, duplication of activities and lack of a flexible review system based on the medication's level of cost, health risk or other order of importance.

- Compared with PA procedures in many other states, Kentucky's PA request procedure is complex, involving the provider, pharmacist, and patient. Two critical pieces of information are required in a PA request; the

diagnosis and the drug's NDC number. The physician doesn't know the NDC number (and perhaps doesn't even know if the drug is a PA list drug or not). Therefore, he or she can't complete a PA request without the pharmacist. Likewise, the pharmacist does not know the diagnosis until he is told by the physician. Therefore, no matter who initiates a PA request, both providers are involved and there is a necessary delay and required communication back and forth between the prescriber and the pharmacist. In the end, the pharmacist must complete the request. In a sense, there are always two PA's going on, one for medical use and the other for payment. In other words, while both a provider and a pharmacist may initiate a PA, only the pharmacist can actually receive a PA approval.

- A mail confirmation is sent to pharmacists in addition to a telephone confirmation. This is a duplication of activity. Additionally, each mail confirmation is sent separately (instead of bundled with other PA requests) adding to personnel and postage costs.

- Finally, DMRAB members have observed that every PA drug is treated with the same degree of effort and scrutiny; e.g., Milk of Magnesia vs Sandimune (an immunosuppressant) children's liquid Motrin vs. Zyprexa (an antipsychoic drug).

Several pharmacists surveyed by Program Review identified some other process problems and provided solution. These included: having physicians put the diagnosis on the PA form or Rx, adding several drugs that are almost never denied to the non-PA list, taking more than 5 PA requests per telephone call, and better informing of physicians regarding the formulary (See Appendix E for a complete listing).

Formulary Management

Concurrent with the growth of the formulary and PA request volume there has been a growth in the size, cost and complexity of formulary management. In addition to growth, DMS has contracted with the UK College of Pharmacy to manage the DMRAB and provide DMS with drug reviews and recommendations.

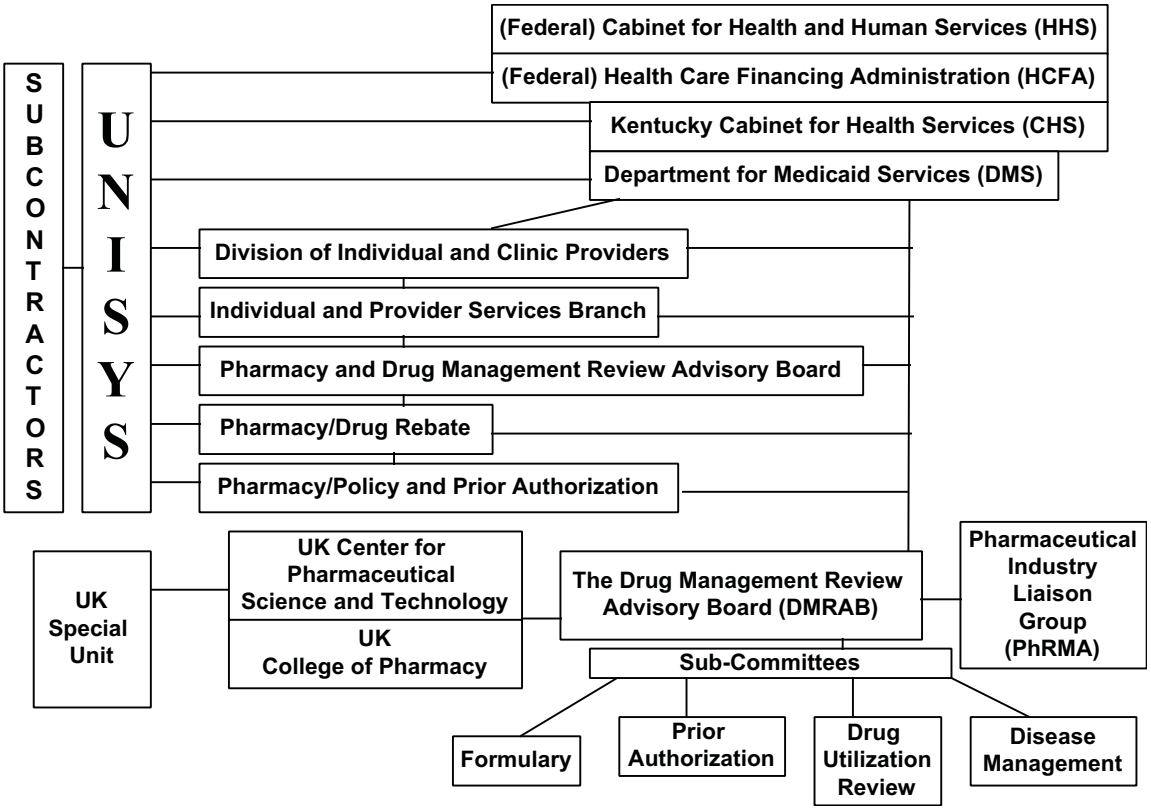
During this recent period of change there has been an increasing politicization of the drug formulary review and recommendation process. Also, despite efforts to make the formulary drug review process more responsive and efficient, the old formulary/PA system remains in place and continues to grow.

Size and Complexity of Management Increases

The size and complexity of the drug lists, the increasing volume of PA requests, along with the increasing growth and automation of Drug Use Review (DUR) and PA functions, have combined to produce an increasingly complex management and committee structure. Several agencies, levels of government, contracts, and committees are now in place to manage the formulary and PA system. Below (Exhibit 5.4) is a diagram of the principal structures involved:

EXHIBIT 5.4

PA/Formulary Structure



Major changes in administration of the process have occurred since 1996. The DMS pharmacy consultant has retired and has not been replaced. Increasingly, the nature of responsibility and the authority for formulary and PA decisions is shifting from the DMS to the UK Center for Pharmaceutical Technology. Prior to being combined with the DURAB into the DMRAB, the Formulary Advisory Board (DFAB) was more directly responsible for developing recommendations through its own meetings and reviews. Meeting deliberations involved extended and detailed discussions of drugs, along with multiple presentations by providers, manufacturers, and consumers. As stated earlier, the DMS now contracts with the University of Kentucky College of Pharmacy to manage the DMRAB (and its sub-committees) and to provide

the DMS and the DMRAB with drug reviews, drug use (DUR) and drug/disease management (DM) recommendations and formulary/PA recommendations.

The 1996-97 contract between DMS and UK was in the amount of $191,380 and required the deliverables and specific budgeted services displayed in Exhibit 5.5 below:

EXHIBIT 5.5

DMS-UK Contract
July 1, 1996 to June 30, 1997

• **Consultation**	
Conduct claims data base outcome studies, 3 @ $5,073 ea.	$15,220
Drug reviews and analysis, 12 @ $1,154 ea.	$13,850
Policy Board Guidelines - therapeutic implementation reviews, 4 @ $2,091	$ 8,363
Implementation of a University system for DUR claims analysis	$28,750
Other - General administrative rate per hour @ $64	$ 2,896
Project rate per hour @ $169	$ 5,072
Newsletter - 3 issues @ $1,725 each	$ 5,175
Total Consultation	**$79,326**
• **Educational Intervention Programs**	
Program/series design and scheduling, 2 @ $16,963	$33,925
Program/series presentation, 2 @ $16,963	$33,925
Total Education	**$67,850**
• **DURAB and DFAB Management**	
Administrative/secretarial support for conducting 9 meetings @ $4,912 per meeting	$44,204
Total DURAB	**$44,204**
• **TOTAL CONTRACT**	**$191,380**

Source: DMS-UK contract

Exhibit 5.6 displays a summary of the status of deliverables and payments at the end of the 1996-97 contract year provided to staff by DMS. Of the contract amount, $175,145 was paid. Services were not performed in the areas of claims data base outcome studies, policy board guidelines or publication of a newsletter. More drug reviews (33%) were conducted, as was one additional meeting.

EXHIBIT 5.6

DMS - UK Contract Summary

Deliverable	Expected Number	Expected Cost	Actual Number	Actual Cost
Conduct claims data base outcome studies	3 @ $5,073	$15,219	0	0
Comments/Description:				
Drug reviews and analysis	12 @ $1,154	$13,848	16	$18,464
Comments/Description: Drug reviews in support of DFAB/DMRAB				
Policy Board Guidelines - therapeutic implementation reviews	4 @ $2,091	$8,364	0	0
Comments/Description:				
Implementation of a University system for DUR claims analysis	1@ $28,750	$28,750	1	$28,750
Comments/Description: Implementation of a data base of claims information in support of the contract				
Other - General administrative rate per hour	@ $64	$2,896	37	$2,368
Comments/Description:				
General Work responding to requests from Medicaid Dept. not covered in other deliverables				
Other - Project rate per hour	@ $169	$5,072	74	$12,529
Comments/Description: Work involving the project team primarily for antihistamines and Acid/peptic initiatives				
Newsletter	3 issues @ $1,725 each	$5,175	0	0
Comments/Description:				
Program/series design and scheduling	2 @ $16,963	$33,925	2	$33,925
Comments/Description:				
1. Attention Deficit Hyperactivity Disorder 2. Obesity				
Program/series presentation	2 @ $16,963	$33,925	2	$33,925
Comments/Description:				
1. Attention Deficit Hyperactivity Disorder 2. Obesity				
Administrative/secretarial support for conducting 9 meetings	@ $4,912 per meeting	$44,204	10	$45,184
Comments/Description:				
7 DMRAB/Subcommittee meetings 1 Cancellation 2 Reschedule				
TOTAL		**$191,380**		**$175,145**

Source: DMS

Scope and Cost of the DMS-UK Contract Increased 61% from FY 97 to FY 98

The 1997-98 DMS-UK College of Pharmacy contract has increased by 61% over 1996-97, from $191,380 to $308,494. The increase in budgeted costs reflects increased drug review requests and the demands of new approaches to PA and drug management. Specific increases were:

- An increase in the number of drug reviews, from 12 in FY 1997 to 60-75 for FY 1998, and an increase in the cost of each review (from $1,154 to over $1,800) resulting from adding administrative charges for processing drug review request submissions ($13,850 in 1997 vs $116,865 in 1998)

- Additional administrative support costs for the chair of the DMRAB ($-0- in 1997 vs $5,750 in 1998)

- Additional meeting management support costs for DMRAB (and sub-committee meetings), from nine in FY 97 to 12 in FY 98 ($44,204 in 1997 vs $58,992 in 1998)

- An increase in Newsletter production (from three in FY 97 to 10 in FY 98, $5,175 in 1997 vs $17,250 in 1998)

Below (Exhibit 5.7) is a listing of 1997-98 contract deliverables and budgeted services. Following this exhibit is a comparison of deliverables and costs between the FY 1997 and FY 1998 contracts (Exhibit 5.8).

EXHIBIT 5.7

DMS-UK Contract - July 1, 1997 - June 30, 1998

PART 1. Consultation			**Total**
1. Algorithm/Guideline development	4 @	$5,019	$20,076
2. Conduct claims data base outcome studies	3@	$4,587	$13,761
3. Drug reviews and recommendations	60@	$1,154	$69,240
4. Drug submissions analysis	75@	$635	$47,625
5. Other - General admin., rate per hour	45@	$64	$2,880
Project rate per hour	30@	$169	$5,070
6. Newsletter per issue	10@	$1,725	$17,250
TOTAL			**$175,902**
PART II. Educational Intervention Programs			
1. Program/series design and scheduling	2@	$16,963	$33,925
2. Program/series presentation	2@	$16,963	$33,925
TOTAL			**$67,850**
PART III. DMRAB & Subcommittee Management			
1. Contractor/staff support per meeting	12@	$4,916	$58,992
2. Administrative Support - DMRAB Chair	1@	$5,750	$5,750
TOTAL			**$64,742**
CONTRACT TOTAL			**$308,494**

SOURCE: DMS - UK Contract

EXHIBIT 5.8
DMS-UK Contract
Comparison of Deliverables and Costs for Fiscal Years 1997 and 1998

CONSULTATION:		1997	1998	INCREASE (DECREASE)
Conduct claims database outcome studies	3 @ $5,073	$15,220		
Conduct claims database outcome studies	3 @ $4587		$13,761	($1,459)
Algorithm/Guideline development	4 @ $5,019		$20,076	$20,076
Drug reviews and analysis	12 @ $1,154	$13,850		
Drug reviews and recommendations	60 @ $1,154		$69,240	$55,390
Drug submission analysis	75 @ $635		$47,625	$47,625
Policy Board Guidelines - therapeutic implementation reviews	4 @ 2,091	$8,363		($8,363)
Implementation of a University system for DUR claims analysis		$28,750		($28,750)
Other - General Administrative rate per hour	45 @ $64	$2,880		.
Other - General Administrative rate per hour	45 @ $64		$2,880	$0
Project rate per hour	30 @$169	$5,070		
Project rate per hour	30 @ $169		$5,070	$0
Newsletter	3 issues @ $1,725	$5,175		
Newsletter	10 issues @ $1,725		$17,250	$12,075
TOTAL CONSULTATION (1997 and 1998)		$79,308	$175,902	$96,594 (122%)
EDUCATIONAL INTERVENTION PROGRAMS				
Program/series design and scheduling	2 @ $16,963	$33,925		
Program/series design and scheduling	2 @ $16,963		$33,925	$0
Program/series presentation	2 @ $16,963	$33,925		
Program/series presentation	2 @ $16,963		$33,925	$0
TOTAL EDUCATION (1997 and 1998)		$67,850	$67,850	$0 (0%)
DURAB, DFAB, and DMRAB MANAGEMENT:				
Administrative/Secretarial support for conducting meetings	9 @ $4,912	$44,204		($44,204)
Contractor/Staff support per meeting	12 @ $4,916		$58,992	$58,992
Administrative Support - DMRAB Chair	1 @ $5,750		$5,750	$5,750
TOTAL DURAB AND DFAB MANAGEMENT		$44,204	$64,742	$20,538 (46%)
TOTAL CONTRACT (1997 and 1998)		$191,362	$308,494	$117,132 (61%)

Source: UK-DMS Contracts; Bold = 1998 Deliverables, budgeted costs, and increase or (decrease) over 1997

PA/Formulary Work Done by Two Committees Now Done by Five

In 1996 the Drug Formulary Advisory Board (DFAB) and the Drug Utilization Review Advisory Board (DURAB) were combined into the Drug Management Review Advisory Board (DMRAB). In 1997, four DMRAB subcommittees were created: Prior Authorization (PA), Formulary (renamed the "Drug File Subcommittee"), Disease Management (DM), and Drug Use Review (DUR). Thus, two committees (meeting a total of eight times per year) have been replaced with five committees, meeting perhaps 20 times per year. The budget of the DMS-UK contract has been increased to reflect this increase in the number of required meetings.

Formulary Drug Review Process Slow, Arbitrary and Politicized

Exhibit 5.9 provides a recent example of the time and effort required to move a recently FDA-approved drug from the PA list to the Non-PA list. Essentially, while the process took eight months in Kentucky, in Ohio and Indiana it took one month. During this time patients, physicians and pharmacists continued to deal with the PA process and its delays. For the pharmaceutical industry, there was substantial investment in time, lobbying, and public relations efforts required to plead their case for the efficacy, need, and cost-effectiveness of the drug in question, first to get it on the review list, then to get it reviewed and approved. Getting a drug on the review list does not ensure quick decision. A drug review may be deferred for months, in order for it to be included as part of a drug class review. For other procedural or administrative reasons, months may go by before a review can be conducted and completed. A drug may not get reviewed, or it may be reviewed and denied entry to the Outpatient Drug List.

In addition to what the process may cost the drug industry (both in lobbying costs and lost drug sales), there are two other fairness issues. First, some drugs are restricted in Kentucky and openly available in most other states. As one drug company representative asked during a recent DMRAB meeting (regarding a drug he had not yet gotten approved in Kentucky), "What is it that Kentucky knows that 47 other states don't?" A second issue involves the competitive fairness of the process. Different manufacturers may release similar drugs. Most reviews are done by drug, not by treatment; therefore it is possible for one drug to be approved for the unrestricted Outpatient List (e.g., recently Zyrtec) while other similar drugs by different manufacturers remain restricted. Manufacturers feel this gives one manufacturer "a franchise" for its drug, to the exclusion of the others.

EXHIBIT 5.9
Drug Review and Recommendation Example

December 17, 1996:	The product (LIPITOR by Parke-Davis) is approved by the FDA.
February 5, 1997:	Application for review and inclusion on the Outpatient Drug List is made to DMS.
February 20, 1997:	Acknowledgment designating LIPITOR as 1-P is sent from the UK Special Unit.
March of 1997:	The Special Unit recommends adding LIPITOR to the Outpatient Drug List; submitted just prior to the DMRAB meeting.
March 25, 1997:	LIPITOR is approved unanimously at the DMRAB meeting.
June 11, 1997:	The Approval is signed by the Secretary of the Cabinet for Health Services the day before the DMRAB meeting.
August 15, 1997:	LIPITOR is added to the Outpatient Drug List.
In this case, the process took eight months (from FDA approval) to complete. By comparison, Ohio (with a closed formulary and PA procedure) and Indiana (with no formulary and no PA procedure) included LIPITOR on their open formularies within 30 days of its introduction.	

Source: Compiled by Program Review staff from information received from Parke-Davis/DMS.

Several very recent revisions have been made to the UK drug review process. The basic procedures now in place (October, 1997) are outlined in Appendix F. Essentially, the new procedures are intended to deal with a higher volume of reviews/recommendations by making them more routine and sending many directly to the DMS rather than through the DMRAB.

These procedures should expedite drug reviews and make the prioritizing of reviews more rational. However, there are still no clear, articulated criteria by which to determine what should and should not "be PA". For example, some argue that drugs with very narrow indications and small consumer populations should be PA drugs. Others use the same parameters to argue that these drugs should be non-PA, open

formulary drugs. Some argue that if a new drug has no major therapeutic advantage over drugs already on the formulary, it should be PA. Others argue that if it is like other drugs in cost and use, it should be on the open formulary along with its competitors.

Creation of new procedures aimed at expediting and rationalizing drug reviews and PA/formulary decisions comes at a time of increasing political involvement in the process. A recent recommendation made on the drug Zyprexa is a case in point (see example). The seriousness of this situation prompted the chair of the Formulary subcommittee to comment at a recent DMRAB meeting:

> . . . an alarming trend seems to be developing that if the industry doesn't like the recommendation of this committee, they're starting to get politicians to come before the committee, or getting physicians to write politicians.

Example:

New criteria for drug reviews and DMRAB policy indicate that some drugs will be considered later as part of a drug/disease class review. However, in response to significant industry pressure applied though both the executive and legislative processes, the drug Zyprexa (and some other drugs) were added to the non-PA list prior to its anticipated class review and without a drug review by UK. In this regard, the October 5, 1997 edition of the Courier-Journal quoted the chair of the DMRAB as saying "The company (Eli Lilly) pushed hard, in my opinion excessively".

The increase in political pressure and lobbying results partly from policy changes governing the process. In order to facilitate open communication and expedite reviews, the DMRAB (unlike its DFAB/DURAB predecessor) now permits and encourages ex parte communication. An ex officio Industry Liaison Group of pharmaceutical company representatives provides advice and information to the DMRAB and its sub-committees. There are no formal restrictions on drug company communication with UK College of Pharmacy faculty who are contracted to staff the DMRAB, manage its meetings, and provide it with drug

product/therapy reviews and recommendations (see note box for previous policy). These faculty recommend to the DMRAB the list placement of drugs reviewed.

An appearance of conflict of interest can arise here, in that drug manufacture's, PhRMA and the NPC also provide grant funds to the College of Pharmacy and its faculty. Additionally, UK faculty involved with the contracting work/process also hold, or have held, membership on the DMRAB (formerly, the DFAB/DURAB). Some attempt to limit these problems has been made. Members of the DMRAB are required to sign conflict of interest forms and some informal "firewalls" between drug review and formulary recommendation activities are in effect.

Note: Prior to the creation of the DMRAB, ex parte communication between drug manufacturers and the DURAB/DFAB was prohibited. Procedurally, this meant that manufacturers could not speak with board members regarding matters before the board(s), and not at all for 30 days prior to board meetings. In practice, it was difficult to enforce the intent of the requirement. Representatives could talk with board members about drugs prior to the 30-day window, and prior to the time when their concerns would formally come before the board. Also, during the thirty-day period, manufacturer's representatives (detailers) continued to be in board members' offices and pharmacies on an ongoing basis and could speak indirectly with them about drugs in question, so long as Medicaid or the boards were not specifically mentioned. In short, the prohibition encumbered communication while not really accomplishing the intended purpose.

Old PA/Formulary Systems Continue While New Systems Are Developed

Concurrent with the shift in responsibility from DMS to UK, there has been a significant shift in the definition of PA and the relationship of PA to the drug lists. Recent DMRAB recommendations to DMS have included disease/drug management (DM), step care protocols, and rational drug therapy approaches to PA and drug therapy (e.g., acid/peptic disorders and the use of antihistamines). These approaches substitute the current individual drug (NDC) phone/fax/mail PA approval procedure

with a pre-determined therapy (disease management) protocol which is to be programmed into the UNISYS Medicaid management information (POS) system. The current (i.e., "old") system continues to operate parallel with the development of new interpretations of formulary and PA processes, processes which will be increasingly dependent on (UNISYS) computer programming, query, reporting, and POS systems.

Although they have discussed these possibilities for change, the Formulary and Prior Authorization subcommittees of the DMRAB have also gone on record in general support of the current system. The published minutes of the May 12, 1997 Prior Authorization Subcommittee meeting include the following statement:

> The Subcommittee agreed that the PA system was desirable as a means to control cost, to minimize fraud and abuse, to minimize polypharmacy, and to identify opportunities for provider education. It was agreed that the system should be retained.

The published minutes of the May 7, 1997 Drug Formulary Subcommittee meeting include the following summary:

> The Subcommittee reviewed the criteria and procedures for handling requests for the addition of drugs to the Drug List. No changes were recommended.

Policy Directions

Since 1996, DMS and other agencies have been moving in substantially new directions. The outcome and utility of these initiatives has yet to be determined. Managed care will have enormous impact on benefit management and the PA/formulary

process. Other forms of controlling cost and treatment quality should receive increased attention as new approaches are developed and cost remains an issue.

Impact of Medicaid Managed Care Unknown

In its effort to control Medicaid costs (through greater efficiencies), the Kentucky Medicaid Program is establishing a managed care approach to providing benefits. As each new so-called Partnership comes on line, pharmaceutical benefits will move from the DMS fee-for-service program to the Partnership managed care program.

Program Review staff requested a position statement from DMS regarding the impact of the managed care approach on the PA/Formulary process. DMS responded as follows:

> Utilization management will be conducted by each regional Healthcare partnership. . . .The partnership in Region 3 has determined it will honor all prior authorizations made by the Department for Medicaid Services for 30 days. At 30 days, the Partnership will review care and make decisions about continuations. The Partnership in Region 5 will honor all prior authorizations for six (6) months and will make decisions about continuations. In those instances, when a Medicaid recipient is transferred from a Partnership to traditional Medicaid services, the Department will honor prior authorizations approved by the Partnerships. Transfers between Partnerships will be handled in the same manner.

The purpose of managed care is to provided quality care and control costs. Thus, it serves the purpose of the PA/Formulary process in a broader fashion. Several policy questions regarding the need or function of PA and the drug lists in the new managed care system are left unanswered at this point:

- Will a PA/Formulary process be necessary? If so will it be at the managed care partnership or DMS level?

- Since managed care organizations are required by federal policy to provide benefits equal to the fee-for-service program, do the PA and non-PA Drug Files constitute the level of drug benefits for which Medicaid (managed care) recipients are eligible?

- May the managed care PA requirements for PA list drugs be different for managed care than they are in the fee-for-service program?

- If the fee-for-service program eliminates PA for a particular drug, or for all drugs, must the managed care organizations do so as well.

- If the fee-for-service program requires co-pays or sets prescription limitations, may managed care do so? Must managed care do so?

- More generally, will benefit changes in the fee-for-service program determine benefit changes in managed care?

- What oversight will the pharmacy/formulary/PA offices at DMS have over the formulary/PA procedures of the managed care organizations?

- How will pharmaceutical/PA claims and encounter/shadow data be managed and reported to (and by) DMS/UNISYS?

Policy Direction Is Needed

The mission and function of the PA/Formulary process seems to be changing or evolving. The goal of controlling costs while ensuring access has been supplemented

with other goals, such as reducing fraud and abuse, controlling polypharmacy, and creating model treatment regimens. As a result, Kentucky seems to be moving rapidly toward a different approach to PA and formulary maintenance, one that focuses on drug use review (DUR), disease management (DM) and drug treatment protocols. Whether this will reduce polypharmacy and control costs remains to be demonstrated. Similarly, even as the above changes are taking place, the old formulary system remains and PA requests are increasing significantly.

Given the growing complexity, costs and bureaucracy of the current system, a clear statement of goals and purposes, and an assessment of administrative alternatives needs to be conducted. For example, if controlling cost is the purpose, it should be acknowledged that data in Chapter 3 and 4 show that several states without PA procedures and formularies still manage to have lower per-recipient drug costs and usage than Kentucky. These states, and other states with significantly different approaches to prior authorization, control their drug benefit costs by focusing on specific identified areas of cost and cost containment, what a Medicaid pharmacist in Indiana called the "scalpel" approach. In a scalpel approach, the location and nature of the unnecessary cost(s) is determined, PA is focused on that area, PA requests are few, and approvals are frequent. Examples of such an approach include focusing on a step-care (rational drug) therapy for a high-cost area, such as acid/peptic disorders, or the limited PA approach of Indiana, which requires a prior authorization in cases where a provider overrides the generic requirement by claiming the drug is Brand Medically Necessary.

Exhibit 5.10 is a list of other cost control programs (tools) that warrant consideration in any comprehensive approach to balancing the purposes of timely access, quality treatment, and cost control.

EXHIBIT 5.10

Other Cost control Mechanisms

REBATE: A monetary amount that is returned to Medicaid from a prescription drug manufacturer, based on utilization by a covered person or purchases by a provider.
RATIONAL DRUG THERAPY: Prescribing the right drug for the right patient, at the right time, in the right amount, and with due consideration of relative cost.
CO-PAY: Cost-sharing that occurs when an insured Medicaid recipient pays a fraction of the cost of prescription drugs out-of-pocket.
DRUG UTILIZATION REVIEW (DUR): An evaluation of prescribing and dispensing patterns to specifically determine the appropriateness of drug therapy. There are three forms of DUR: prospective (before or at the time of prescription dispensing), concurrent (during the course of drug therapy), and retrospective (after the therapy has been completed).
MANAGED CARE (ORGANIZATION) MCO: A health-care plan which integrates the financing and delivery of care so as to maximize the value of its services within a fixed budget. In addition to formularies, MCOs also use other techniques to limit prescription drug costs, including: therapeutic substitution, step-care therapy, drug utilization review, and generic substitution.
GENERIC DRUG PREFERENCE: A chemically equivalent version of a brand-name drug, must be used if available. A brand medically necessary drug may be authorized if requested by physician and supported by medical justification.
PRESCRIPTION LIMITATIONS: The maximum number of prescriptions and the maximum number of refills per patient, permitted within a determined time period (usually one month).
STEP-CARE PROTOCOL/THERAPY: Step-Care Protocol requires that physicians follow a sequence of (drug) treatments for a given condition, usually starting with the lowest cost treatment, and progressing to higher cost treatments only if previous treatments were not effective.
THERAPEUTIC INTERCHANGE: This is the creation of a special professional relationship between the pharmacist and the physician. The pharmacist discusses the drug alternatives with the physician to determine most appropriate. Therapeutic Interchange seeks to achieve an effective and economic use of medicines in order to provide the optimum therapeutic benefit to patients.
PHARMACY BENEFIT MANAGERS (PBMs): Specialized companies that manage pharmaceutical benefits. PBMs, which grew out of insurance claim processing and mail-order prescription companies, market their services to employers, insurance companies, managed-care groups, and Medicaid.
MAXIMUM ALLOWABLE COST (MAC): A maximum cost is fixed for which the pharmacist can be reimbursed for selected products, as identified in a drug formulary.
FOCUSED PRIOR AUTHORIZATION: PA procedures that focus on cost containment/cost center locations and drug classes, rather than individual drugs or NDCs. For example, requiring prior authorization for a Brand Medically Necessary (BMN) override of a generic equivalent requirement, a PA requirement for expensive or long-term maintenance drugs and addictive or abused drugs.

Source: Compiled by Program Review staff.

RECOMMENDATION 1: DMS NEEDS TO DETERMINE PROBLEMS, SET GOALS, AND DEVELOP EFFECTIVE STRATEGIES

The DMS should undertake a review of the PA/Formulary process and the Medicaid drug program. This review should be completed by May of 1998 and should accompany a plan of action to be implemented in the next fiscal year. The review and plan of action should:

- **Determine the factors that cause Kentucky's high drug costs and usage rate;**

- **Establish goals, objectives, performance targets, and timelines for addressing cost control;**

- **Determine the management structure and program strategies to use to meet the goals and targets, in the most effective and efficient manner; and**

- **Establish methods to measure accomplishment of these goals and targets.**

APPENDIX A

Kentucky Medicaid Prior Authorization (PA) Process

Kentucky Medicaid Prior Authorization form

APPENDIX B

Kentucky Pharmacists Association, Inc., Position Statement

APPENDIX C

PhRMA Position Statement

APPENDIX D

Coopers and Lybrand Evaluation Recommendations

APPENDIX E

Suggestions Made By Surveyed Pharmacists

APPENDIX F

Flow Chart on The Process for the Drug File

Definitions on Flow Chart

Flow Chart - Process for Managing Line Extensions

Flow Chart - Process for Managing DMRAB Recommendations

APPENDIX G

Bibliography

APPENDIX H

Recommendation Worksheet

PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE

KENTUCKY MEDICAID DRUG FILE AND PRIOR AUTHORIZATION SYSTEM

RECOMMENDATION WORKSHEET

NOVEMBER 13, 1997

RECOMMENDATION #1: DMS NEEDS TO DETERMINE PROBLEMS, SET GOALS, AND DEVELOP EFFECTIVE STRATEGIES

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- **Establish methods to measure accomplishment of these goals and targets.**

AGENCY RESPONSE:	STAFF RESPONSE/COMMITTEE ACTION:

DMS RESPONSE