United States General Accounting Office

GAO

Report to the Chairman, Committee on the District of Columbia, House of Representatives

August 1994

PRESCRIPTION DRUGS

Automated Prospective Review Systems Offer Potential Benefits for Medicaid

GAO/AIMD-94-130

GAO

United States
General Accounting Office
Washington, D.C. 20548

Accounting and Information
Management Division

B-257257

August 5, 1994

The Honorable Pete Stark
Chairman, Committee on the District of Columbia
House of Representatives

Dear Mr. Chairman:

Concerned with the impact of adverse drug reactions on patient safety, as well as the billions of dollars spent annually on Medicaid prescription drug benefits, the Congress amended the Social Security Act to require states to implement drug utilization review (DUR) programs not later than January 1, 1993. Under these programs, states are required to review Medicaid prescriptions to (1) determine whether they are appropriate, medically necessary, and not likely to result in adverse medical reactions and (2) identify fraud, waste, and abuse. These reviews are to be performed before prescriptions are filled (prospective), as well as on a quarterly basis after they are filled (retrospective).

The purpose of this report is to discuss states' use of information technology in implementing their DUR programs, the effectiveness of using automated systems to perform prospective reviews, and the extent to which the Department of Health and Human Services' (HHS) Health Care Financing Administration (HCFA) has encouraged the use of automated prospective DUR systems. This report also responds to your September 21, 1993, request that we consider the District of Columbia in our review of the states' implementation of DUR systems.

Results in Brief

Inappropriate drug therapy poses a significant health risk to Medicaid patients and could be adding potentially hundreds of millions of dollars annually in unnecessary drug and hospitalization costs. Pharmacies' use of automated systems linked to a statewide database could provide a more thorough prospective review than reviews based on manual or local systems; however, the use of statewide automated prospective DUR systems is not statutorily required. Even though such systems are optional, two-thirds of the states and the District of Columbia have or plan to have them. Officials from most of the remaining states said they do not plan to acquire statewide automated prospective DUR systems because they believe the systems are too costly to acquire and operate and may not provide tangible benefits.

Data provided by five states we visited that operated statewide prospective DUR systems for portions of fiscal year 1993 show that these systems resulted in the cancellation of over 128,000 prescriptions that posed a risk of serious adverse medical reactions. Also, two of these states provided data showing that their systems led to the cancellation of over 250,000 early refill prescriptions as potential fraud or abuse.[1] In addition to increasing patient safety, such cancellations can result in program savings to the extent that the prescriptions are not subsequently filled or replaced with a substitute. For example, prescriptions canceled by these five states during portions of fiscal year 1993 were valued at about $12 million. While data were not available to show the actual savings resulting from these cancellations, we believe the sheer magnitude of cancellations indicates a significant savings potential for the Medicaid program.

With reported Medicaid hospitalization costs totaling nearly $39.6 billion for fiscal year 1993, and estimates of hospitalizations due to inappropriate drug therapy ranging from 3 percent all the way up to 28 percent (for the elderly population), automated prospective DUR reviews could help prevent unnecessary hospitalizations, with substantial potential program saving. HCFA has taken some actions to encourage the use of automated prospective DUR systems for the Medicaid program, such as conducting a demonstration project with Iowa. However, states are looking to HCFA to provide more information to aid them in acquiring and implementing these systems.

Background

The Medicaid program, authorized in 1965 under Title XIX of the Social Security Act, is a federally aided, state-run medical assistance program. About 30 million people received an estimated $84.4 billion (federal dollars) in Medicaid services during fiscal year 1993. At the federal level, HCFA is responsible for administering the Medicaid program, establishing policies, developing operating guidelines, and ensuring states' compliance with Medicaid regulations.

Federal regulations require states to provide certain basic medical services, such as inpatient hospital services and physician services, under their Medicaid programs. Federal regulations also authorize states to provide numerous optional medical services, such as optometrist services and eyeglasses and prescribed drugs. During fiscal year 1993, all states

[1]Early refills include prescriptions submitted (1) for the exact same drug, (2) for the same person, and (3) by either the same or a different pharmacy before a predetermined amount of the drug, such as 75 percent, has been consumed. While there may be a legitimate need for an early refill in some situations, early refills also include duplicate prescriptions submitted for purposes of fraud or abuse.

provided prescribed drugs as part of their Medicaid programs; the reported cost of these drugs totaled about $6.9 billion for fiscal year 1993.

Because of growing concern over the increased use and costs of prescribed drugs, in 1990 the Congress amended the Social Security Act to require states to implement drug utilization review programs by January 1, 1993.[2] These programs must have both prospective and retrospective drug reviews that include screening for drug therapy problems due to therapeutic duplication, drug-disease contraindication, drug-drug interaction, incorrect drug dosage, incorrect duration of treatment, drug-allergy interactions, and clinical abuse/misuse.[3] To meet the requirement for retrospective reviews, states are required to use their mechanized claims processing information retrieval systems—typically called Medicaid Management Information Systems (MMIS)—or other automated systems integrated with these systems. The law encourages, but does not require, states to use automated systems to conduct prospective reviews.

Prospective reviews are to occur before prescriptions are filled or delivered to recipients. Retrospective reviews are to occur at least quarterly after prescriptions are filled. The act states the purpose of both reviews is to ensure that prescriptions are appropriate, are medically necessary, and are not likely to cause adverse medical results. The act also directs that states' DUR programs be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients or associated with specific drugs or group of drugs.

Scope and Methodology

We contacted the Medicaid DUR coordinators in all 50 states and the District of Columbia to determine their plans for implementing statewide automated prospective DUR systems. In addition, to obtain data on system operations, costs, and potential benefits, we visited five of the eight states that had statewide automated prospective DUR systems in operation during 1993: Maryland, Missouri, Pennsylvania, Tennessee, and West Virginia.

We contacted three vendors who design and market prospective and retrospective systems to obtain information on the capabilities of these systems. In addition, we interviewed officials at HCFA's headquarters office

[2]Public Law 101-508, November 5, 1990, (Omnibus Budget Reconciliation Act of 1990).

[3]Appendix I provides definitions for each drug therapy problem.

in Baltimore, Maryland, to determine the extent to which HCFA has provided guidance and technical assistance to the states on acquiring information technology for their DUR programs.

The five states we visited provided data on the operations of their statewide automated prospective DUR systems—data generated by the contractors that operate these systems for the states. These data show the results of drug utilization reviews performed by these systems, but differ by state both in the kinds of information reported and the periods of operation during 1993. Given these variances and the number of systems, we provide these data only to indicate the potential results of such systems; we did not attempt to verify these data.

We conducted our review between March 1993 and May 1994, in accordance with generally accepted government auditing standards. The Department of Health and Human Services provided comments on a draft of this report. These comments are presented and evaluated in the body of the report and are reprinted in appendix VI.

Use of Automated Prospective DUR Systems Could Increase Patient Safety

While considerable public policy attention has focused on the issues of overall expenditures and price levels for pharmaceuticals, there is a growing concern that inappropriate drug therapy may reduce the potential benefits of available drugs or, even more importantly, cause serious harm or even death to patients. By using a statewide database and automating the review of prescriptions before they are filled, prospective DUR systems can perform more thorough reviews to help reduce the risk of inappropriate drug therapy and increase patient safety.

Inappropriate Drug Therapy Threatens Patient Safety

Patients may inadvertently be prescribed the wrong drug, the wrong dosage, or a drug that will interact adversely with another drug they are taking. The effects of such inappropriate prescribing can be serious—hospitalization may be necessary and sometimes death can occur. Depending on the study and the patient population considered, estimates of the extent of hospitalizations resulting from inappropriate drug therapy range from 3 percent for the general population to as high as

28 percent for the elderly population.[4] In addition, the Food and Drug Administration (FDA) operates a voluntary system for health care professionals (physicians, nurses, and pharmacists) to report suspected adverse drug experiences. During fiscal years 1990 through 1992, these health care professionals reported 175,614 cases of adverse drug experiences. While all adverse drug experiences may not be reported, of these reported cases, 24,419 (14 percent) resulted in hospitalizations and 5,684 (3 percent) resulted in death.

The Automated Prospective DUR Process

A statewide automated prospective DUR system, integrated with a state's MMIS, can assist pharmacists in submitting Medicaid prescription drug benefit claims and in assessing the full range of medications a patient is receiving through the Medicaid program. It also supports expanded patient counseling. The automated prospective DUR process is described below and illustrated in appendix III.

For automated prospective DUR systems, when a Medicaid patient submits a prescription to be filled, the pharmacy transmits patient identification and prescription information to the statewide MMIS database.[5] The information is transmitted via computer terminal and point-of-sale equipment (similar to equipment currently used to authorize credit card purchases). In an on-line, real-time mode, the system will edit the benefit claim, verify the recipient's eligibility, determine whether the claim is payable (adjudication), and automatically screen the prescription against the patient's known Medicaid medical and prescription history and drug utilization review criteria. According to contractor data, in usually just seconds, the system responds to the pharmacy indicating whether the recipient is eligible and the claim payable, and whether there is a potential drug therapy problem such as drug-to-drug interaction.

[4]Caranasos, G. J., M.D.; R.B. Stewart, M.S.; and L.E. Cluff, M.D. "Drug-Induced Illness Leading to Hospitalization." Journal of the American Medical Association, Vol. 228, No. 6. (May 6, 1974); and Col, M.; J.E. Fanale; and P. Kronholm. "The Role of Medication Noncompliance and Adverse Drug Reactions in Hospitalizations of the Elderly." Archives of Internal Medicine, Vol. 150, No. 4. (Apr. 1990) 841-845, respectively. See appendix II for a list of studies related to hospitalizations due to adverse drug events.

[5]Given the sensitive nature of Medicaid data files in the state's MMIS, the automated prospective DUR system restricts access to authorized users. We did not assess the adequacy of data security for any state system, but according to one contractor that operates systems for two states, such systems use commercially available software security systems to limit unauthorized access. According to this contractor, these security systems require the use of passwords to access MMIS and track such access by password, transaction, data set, and individual. They also produce audit trail reports that show both successful and unsuccessful access attempts.

If the recipient is ineligible or the claim is not payable, the claim is denied. If there is a potential drug therapy problem, the pharmacist consults with the recipient and/or the recipient's physician according to the seriousness of the problem. Depending on the outcome of this consultation, the pharmacy may then fill the original prescription, resubmit the claim for a new drug prescribed by the physician, or submit a reversal to cancel the claim.

Figure 1 provides an example of the information a pharmacy receives on its computer terminal when a potential drug therapy problem is identified. In this example, on April 1, 1993, the recipient submitted a prescription for an acne treatment drug that can cause birth defects. The information provided to the pharmacist by the prospective DUR system showed that in March 1993 the recipient obtained a prescription for a prenatal vitamin, indicating that the recipient was pregnant. This information was available even though, as the physician and pharmacy codes indicate (code 3), the recipient obtained the vitamin prescription from a different physician and a different pharmacy than for the acne treatment drug.

Figure 1: Example of Prospective DUR Computer Screen

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Status   : Claim Payable          Date of Previous Fill    : 03-23-93
Recipient ID     : 123121234              Amount of Previous Fill  : 00030
Drug Name        : Nozits                 Conflict Code            : PG
                         Physician Code           : 3
                         Pharmacy Code            : 3

Message 1 : Possible Pregnancy Conflict / Prenatal Vitamin
Message 2 :
Message 3 :


Total Price              Deducted         Billed           Generic Diff.
 $130.00                  $2.00            $128.00          $1.00

Consult Fee              Allowed          Payment          Fee Paid
 $0.00                    $121.50          $119.50          $2.50
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For pharmacies in states that do not use an automated prospective DUR system, pharmacists are generally limited to comparing the prescription to medical history and prescription information maintained at their specific pharmacy or chain of pharmacies. Automation may help screen for potential adverse drug reactions, but a local system would not have the benefit of the patient's complete Medicaid medical and prescription history as contained in a state MMIS. Moreover, there would be no on-line eligibility verification or claim submission/adjudication.

State Systems Identify Inappropriate Drug Therapy

Contractor-reported results from operations of statewide automated prospective DUR systems in Maryland, Missouri, Pennsylvania, Tennessee, and West Virginia indicate that these systems can reduce the threat of inappropriate drug therapy for Medicaid patients. During portions of 1993, these states' systems identified over 1 million prescriptions that posed a potentially serious risk to patient safety, with pharmacies canceling over 128,000 of these prescriptions. For example, during the period May through October 1993, the Tennessee system showed pharmacies canceled a reported 6,263 prescriptions in which there was a risk of severe drug-drug interactions and 299 prescriptions with a risk of serious birth defects. Similarly, during the period January through October 1993, the Maryland system showed pharmacies canceled a reported 14,516 prescriptions where there was a risk of severe drug-drug interactions and 132 prescriptions with a risk of serious birth defects. (Appendix IV contains detailed contractor data on DUR system operations for four of the five states contacted in our review. The fifth state—West Virginia—changed DUR contractors during 1993 and did not have consistent data available for operations during the year.)

Comparison data were not readily available for prospective reviews performed by pharmacies without an automated system or by pharmacies with a local system for the individual pharmacy or chain. However, officials from several states said they do not believe states can effectively meet requirements to conduct prospective drug utilization reviews without the use of statewide automated prospective DUR systems because individual pharmacies do not have access to a Medicaid recipient's complete medical and pharmacy history unless the recipient obtains all his/her prescriptions from the same pharmacy, which is unlikely for many recipients. For example, Tennessee's data show that more than 47 percent of all its Medicaid recipients used more than one pharmacy during a 12-month period. In addition, Maryland's Medicaid data showed that 1,525 recipients visited three or more different pharmacies during a 1-month

period, and 5,199 recipients visited three or more physicians during the same month.

Prospective DUR Systems May Result in Substantial Savings

Automated prospective DUR systems may result in actual savings when pharmacies cancel prescriptions identified as inappropriate drug therapy. Such savings may occur from the value of those prescriptions canceled and not subsequently filled with another prescription. However, even more substantial program savings may occur when a hospitalization due to an adverse drug reaction is prevented. Other savings may also be attributed to the value of cancellations because of potential fraud, waste, and abuse. When costs to acquire and operate automated prospective DUR systems are compared to these potential savings, the systems appear to be very cost-effective.

Value and Potential Savings Implications of Inappropriate Drug Therapy Cancellations

Table 1 shows contractor data on (1) the number of Medicaid prescriptions canceled after being identified as inappropriate drug therapy and (2) the associated value of these cancellations for five states' automated prospective DUR systems during varying periods of operation for 1993. As this information demonstrates, the value of these cancellations can be substantial—at least $3.5 million for these states. We recognize the value of such cancellations may not always result in actual savings to the program. For example, prescriptions identified as inappropriate drug therapy may be replaced with another prescription. However, we believe the value of cancellations do indicate potential program savings.

Table 1: Summary of Contractor Data on Number and Value of Prescriptions Canceled as Inappropriate Drug Therapy

State	Period of operation	Number of prescriptions canceled	Value of prescriptions canceled
Maryland	Jan. 1, 1993-Oct. 31, 1993	51,519	$1,614,753
Missouri	Mar. 1, 1993-Oct. 31, 1993	30,271	860,495
Pennsylvania	Sep. 1, 1993-Oct. 31, 1993	17,414	N/A[a]
Tennessee	May. 1, 1993-Oct. 31, 1993	25,824	932,726
West Virginia	Jan. 1, 1993-Feb. 28, 1993	3,296	$104,634
Totals:		**128,324**	**$3,512,608**

[a]At the time of our review, Pennsylvania was not preparing reports showing the value of prescription cancellations.

In addition to these potential direct savings from canceled prescriptions, numerous studies indicate that a percentage of all hospitalizations are due to inappropriate drug therapy, such as adverse drug-drug interactions (see appendix II). For example, in September 1990 congressional hearings on the Medicaid budget initiative, the chief executive officer of the American Pharmaceutical Association, National Professional Society of Pharmacists, estimated that nearly 20 percent of all hospital admissions can be traced to some kind of drug misadventure.[6] We recognize that hospitalizations from inappropriate drug therapy may involve a host of different factors that prospective drug utilization review may not identify, such as drug use in combination with alcohol or over-the-counter medication. However, with Medicaid hospitalization costs of nearly $39.6 billion for fiscal year 1993, we believe automated prospective DUR systems could help prevent some hospitalizations due to inappropriate drug therapy, which could, in turn, result in substantial potential program savings.

Potential Savings by Preventing Fraud, Waste, and Abuse

Automated prospective DUR systems can also provide savings by preventing potential fraud, waste, and abuse. While some early refill claims may be legitimate and ultimately refilled, others can involve potential fraud or abuse. In our August 1993 report on drug fraud in the

[6]Medicaid Budget Initiatives: Hearings before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, September 10 and 14, 1990.

Medicaid program,[7] we cited an instance in which a recipient submitted six prescriptions for the same drug within a 4-day period at six different pharmacies. This recipient also obtained a total of 85 prescriptions within an 18-day period that cost the Medicaid program $1,314.

An automated statewide prospective DUR system could prevent such fraud and abuse by denying many claims as early refills. For example, the Maryland and Tennessee systems automatically deny early refill claims. For 10 months of operation during 1993, contractor reports show that the Maryland system denied 144,880 early refill prescriptions valued at about $5.2 million. Similarly, for 6 months during 1993, contractor reports show that the Tennessee system denied 108,456 early refill prescriptions valued at $3.1 million.

Preliminary Data Show Systems Can Be Cost-Effective

Preliminary cost data gathered from states during our review indicate that automated prospective DUR systems are relatively inexpensive and are cost-effective to implement and operate when compared to potential cost savings.[8] Moreover, the actual cost to the states can be even lower because federal funding for the Medicaid program can reimburse up to 90 percent of system development/implementation costs and 75 percent of system operating costs.

According to information contained in the advance planning documents submitted to HCFA by the five states we visited, their total one-time system development and implementation costs ranged from $105,000 to $675,000. Most of these states also provided actual or estimated system operation costs for 1993. Comparing such costs to the potential benefits realized by the systems indicate the potential cost-effectiveness of automated prospective DUR systems. For example, the total one-time system installation cost for Tennessee's system was about $420,000, and the total operational cost for its initial 6 months of operation was about $578,000. In contrast, contractor data show the value of prescriptions canceled during this 6-month period exceeded $4 million. For Maryland, the total one-time system acquisition cost was about $165,000, and the total operational cost for the system's initial 10 months of operation was about $472,000. Contractor data show the value of prescriptions canceled during this period exceeded $6.7 million.

[7]Medicaid Drug Fraud: Federal Leadership Needed to Reduce Program Vulnerabilities (GAO/HRD-93-118, Aug. 2, 1993).

[8]We did not independently verify these cost data.

The development and operational costs shown above for the Tennessee and Maryland prospective DUR systems also include costs to install and operate on-line, real-time Medicaid eligibility verification and claims submission and adjudication. Both of these capabilities can provide substantial additional benefits. For example, according to a May 1992 HHS Office of Inspector General report, Massachusetts' on-line Medicaid eligibility verification system saved the state $8.5 million during its first year of operation.[9] These savings were attributable to identifying individuals who were not eligible for Medicaid benefits before they obtained Medicaid services. In addition, on-line claims submission and adjudication eliminates costs states incur to keypunch paper Medicaid drug claims. According to a senior programmer/analyst for the Missouri prospective DUR contractor, on-line claims submission/adjudication allowed the firm to eliminate five keypunch operator positions.

HCFA Could Influence State Implementation of Automated Prospective DUR Systems

The Social Security Act does not require states to use automated systems to perform prospective drug utilization reviews. At the time of our review, about one-third of the states did not have plans to acquire automated systems for this purpose. While HCFA has provided some information to the states on the use of automated prospective DUR systems, it has generally provided little guidance. Additional information, especially on costs and benefits, could encourage more states to adopt these systems. Additional guidance would also help standardize procedures for implementing the systems.

As of December 31, 1993, eight states were operating automated prospective DUR systems. Medicaid DUR coordinators from 22 other states plus the District of Columbia[10] told us they plan to begin operating such systems—most sometime during 1994 and 1995. DUR coordinators from the remaining 20 states told us their states did not have any plans to acquire and operate these systems.[11] Appendix V lists the status of states that are implementing automated prospective DUR systems.

[9]Point-of-Service Claims Management Systems for Medicaid, Department of Health and Human Services, Office of Inspector General, May 1992.

[10]According to the DUR Coordinator for the District of Columbia's Office of Medical Assistance, the District's City Council has approved funding for an automated prospective DUR system. Work has begun for the District's MMIS contractor to integrate the prospective DUR system with the MMIS. This official estimates the system will begin operations in September 1994.

[11]Four of these states are not required to perform drug utilization reviews because most of their Medicaid patients are covered under some type of a health maintenance organization plan. The Social Security Act does not require states to conduct drug utilization reviews for covered outpatient drugs that are dispensed by health maintenance organizations.

Despite the significant potential benefits and relatively low cost of automated prospective DUR systems, DUR coordinators from 11 of the 16 states not planning to acquire these systems said their decision was based on the belief that the systems would not provide tangible benefits to offset system costs. For fiscal year 1992, these 16 states' Medicaid programs dispensed about 82 million prescriptions to over 5.6 million Medicaid patients. DUR coordinators from five of these states said that HCFA had not provided them information on the costs and benefits of automated prospective DUR systems. These officials added that if they had data showing the systems were cost-effective, they might reconsider their decision.

DUR coordinators from four of the states we contacted specifically said that information on the capabilities and desirable features of automated prospective DUR systems would be beneficial. Since automated prospective DUR systems are not statutorily required, there are no federal standards or guidelines for implementation. As a result, system functions can vary by state. For example, data for the five state systems we reviewed showed that four systems screen for pregnancy conflicts; the remaining state does not. Also, one of the five state systems automatically suspends a claim if a drug therapy problem is identified. The system requires the pharmacist to enter a code into the system to override the alert and adjudicate the claim for payment. If the alert is not overridden within 48 hours, the system automatically cancels the claim. In contrast, the other four systems automatically adjudicate a claim for payment even though there may be a drug therapy alert. These systems require pharmacists to enter a code to reverse (cancel) the claim only if they believe a serious problem exists.

HCFA has taken some steps to provide information on the use of automated prospective DUR systems. For example, HCFA cosponsored a 2-day seminar on the use of these systems and conducted a demonstration project with the state of Iowa. However, according to the HCFA official responsible for overseeing states' DUR programs, HCFA has not had the staff needed to take a more active role in encouraging states to acquire automated prospective DUR systems or to issue standards or guidelines on their use.

Conclusions

Although data are not yet available to conclusively show the costs and benefits of using statewide automated prospective DUR systems for Medicaid prescriptions, these systems offer a significant opportunity to increase patient safety. Limited operation of automated prospective DUR systems by several states demonstrates this and indicates the significant

cost savings potential of these systems. More than two-thirds of the states and the District of Columbia agree that these systems are beneficial and either operate or plan to implement automated prospective DUR systems within the next few years. Additional information about system use and benefits would encourage more states to consider these systems. In addition, all states could benefit from federal system guidance to help ensure standard implementation of effective systems.

Recommendations

To increase patient safety and the potential for significant program savings, we recommend that the Secretary of the Department of Health and Human Services direct the Administrator of the Health Care Financing Administration to (1) gather information on the costs and benefits of automated prospective DUR systems, (2) develop guidance on desirable features and capabilities for these systems, and (3) provide this information and guidance to all states.

Agency Comments and Our Evaluation

In commenting on a draft of our report, the Department of Health and Human Services generally agreed with our recommendations and the facts presented. The Department agreed that data are not yet available to conclusively show the benefits and costs of using statewide automated DUR systems, that these systems offer a tremendous opportunity to improve patient safety, and that all states could benefit from federal system guidance.

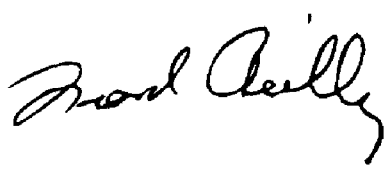
The Department said that it had contracted for the development of methodological guidance on how to evaluate the cost-effectiveness of conducting prospective DUR through electronic systems, and that it would distribute the resulting report to all state Medicaid programs when available. The Department also noted that it expects to receive shortly each State's annually required report on their DUR program. It agreed that these reports should provide better information on states' experiences with on-line prospective DUR, and that the Department would share its analysis of these reports with all of the states as soon as possible.

The Department did not address our recommendation concerning development and distribution of guidance regarding desirable features and capabilities of automated DUR systems. Because patient safety is a primary concern, it is important that the Department expeditiously develop and transmit such guidance to all states.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the date of this letter. We will then send copies to the Secretary of Health and Human Services; the Director, Office of Management and Budget; other interested congressional committees; and state Medicaid directors and DUR coordinators. Copies will also be made available to others upon request.

Please contact me at (202) 512-6252 if you or your staff have any questions concerning this report. Other major contributors to this report are listed in appendix VII.

Sincerely yours,



Frank W. Reilly
Director, Information Resources Management/
Health, Education, and Human Services

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Abbreviations

DUR	drug utilization review
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
MMIS	Medicaid Management Information Systems

Glossary of Drug Utilization Review Terms

Adverse Drug-Drug Interaction	The potential for, or the occurrence of, an adverse medical effect as a result of the recipient using two or more drugs together.
Adverse Medical Result	A clinically significant undesirable effect experienced by a patient due to the course of drug therapy.
Drug-Age Contraindication	Use of a drug that is not recommended for the age group of the patient. This can occur when the patient is too old or young for the given medication.
Drug-Allergy Interactions	The significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.
Drug-Disease Contraindication	The potential for, or occurrence of, an undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition or the potential for, or the occurrence of, an adverse effect of the drug on the patient's disease condition.
Gross Overuse	Repetitive overutilization without therapeutic benefit.
Incorrect Drug Dosage	Dosage that lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days of supply.
Incorrect Duration of Drug Treatment	The number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.
Overutilization	Use of a drug in quantities or for durations that put the recipient at risk of an adverse medical result.
Pregnancy Conflict	Use of prescribed drug that is not recommended during pregnancy.
Therapeutic Duplication	The prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at

	risk of an adverse medical effect or incurs additional program costs without additional therapeutic benefit.
Underutilization	A drug used by a recipient in insufficient quantity to achieve a desired therapeutic goal.

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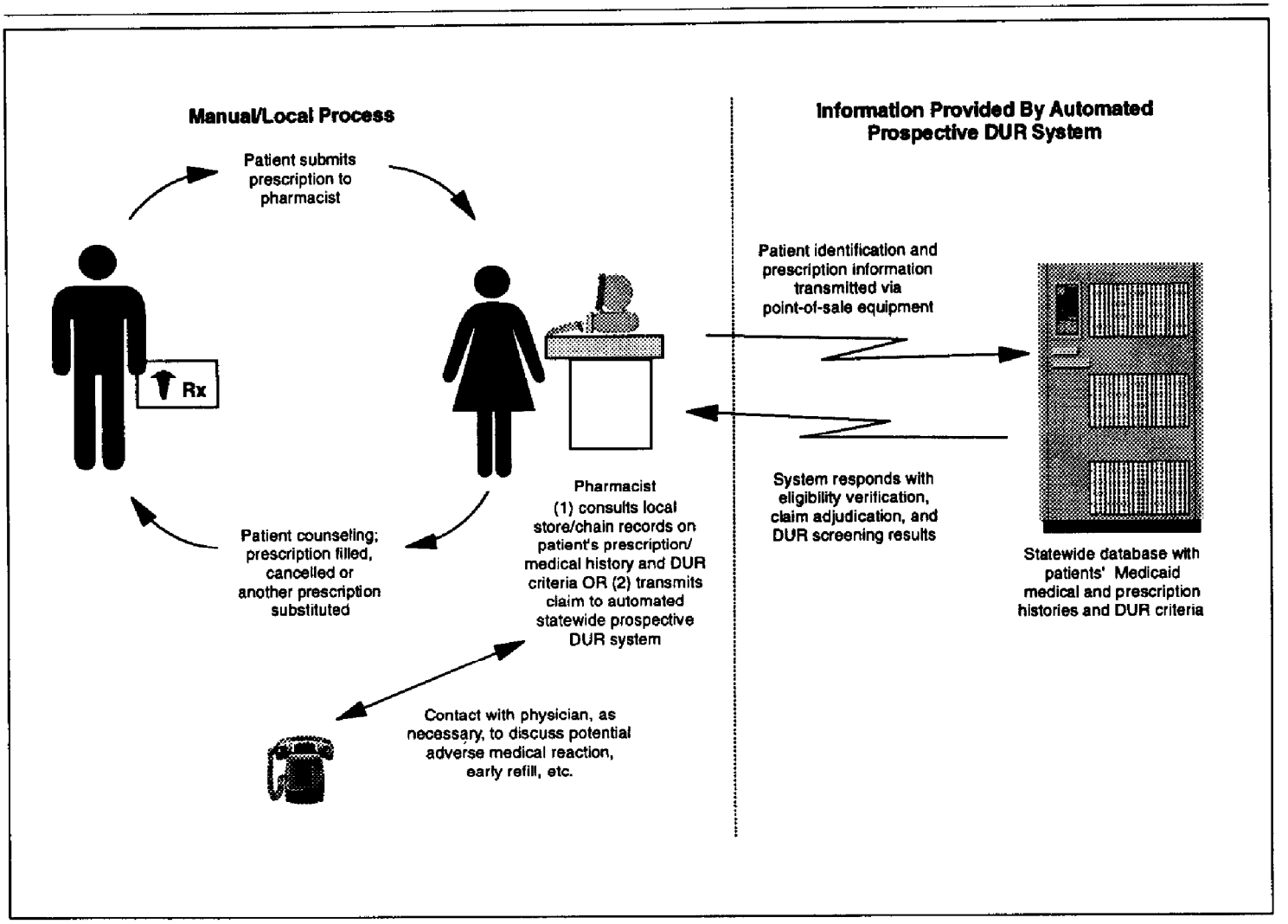
Processing a Medicaid Prescription Drug Benefit Claim Using a Statewide Automated Prospective DUR System



Warnings and Claim Cancellations Resulting From States' Prospective DUR Systems

The following tables provide detailed contractor data on the results of automated prospective DURs as provided by four of the five states we visited that operated such systems during 1993. West Virginia data are not presented because it changed DUR contractors during 1993 and did not have consistent data available for operations during the year. These data include (1) the number and types of drug therapy alert messages sent via states' prospective DUR systems, (2) the number of claims reversed and the value of these reversals, and (3) the number and value of early refill prescriptions denied and not resubmitted. Table content may vary between states due to differences in the types of data reported by states' systems. Also, the periods of operation during 1993 differ by state. Given these variances and the number of systems, we did not attempt to verify these data.

Table IV.1: Maryland Prospective DUR System Warnings and Cancellations From January 1, 1993, to October 31, 1993

Total claims processed	3,365,929
Total cost of claims processed	$95,025,298

	Total claims reversed	Value of reversals
Drug therapy alerts		
Drug-drug interactions	14,516	$456,534
Pregnancy conflict	132	1,346
Therapeutic duplication	5,480	258,510
Underutilization	4,486	141,940
Excessive daily dose	7,082	168,058
Excessive daily dose over age 65	7,338	385,252
Excessive daily dose children	225	4,640
Excessive quantity dispensed	3,337	86,347
Insufficient daily dose for age	8,654	105,377
Drug-disease interaction	269	6,749
Total	51,519	1,614,753
Early refills denied	144,880	5,173,146
Total claims reversed/value	**196,399**	**$6,787,899**
Reversals/value of reversals as a percent	5.83	7.14

Table IV.2: Missouri Prospective DUR System Warnings and Cancellations for the Period March 1, 1993, to October 31, 1993

Total claims processed			3,340,917
	Number of warnings sent	**Number of claims reversed**	**Total value of reversals**
Drug therapy problem			
Drug disease conflict	3,773	138	$3,449
Drug indicated disease conflict	41,814	1,316	35,515
Below minimum dose range	7,294	244	6,186
Above maximum dose range	3,473	96	7,464
Below minimum daily dose	151,700	5,406	92,431
Above maximum daily dose	136,470	5,585	183,010
Significant side effect	7,681	91	1,767
Additive side effect	1,340	29	867
Side effect medical condition	261	1	4
Indicated for prior drug's side effect	279	3	21
Drug-drug interaction	46,205	1,320	30,619
Duplicative therapy same drug	241,421	11,386	294,041
Therapeutic duplication	77,106	2,908	76,684
RX initiates 90-day therapy	11,916	268	19,118
RX applies to 90-day therapy	22,516	473	34,906
Current RX exceeds 90-day therapy	37,509	675	59,422
Maintenance dose	20,211	332	14,991
Total	**810,969**	**30,271**	**$860,495**

Table IV.3: Pennsylvania Prospective DUR System Warnings and Cancellations for the Period September 1, 1993, to October 31, 1993

	Total alerts sent	Total claims reversed	Percent alerts reversed
Drug therapy alerts			
Drug-drug interaction	3,412	643	18.85
Low dose alert	21,827	4,810	22.04
High dose alert	25,177	6,924	27.50
Drug age precaution	135	22	16.30
Drug pregnancy alert	19	9	47.37
Therapeutic duplication	24,810	5,006	20.18
Total	75,380	17,414	23.10
Early refills	14,042	5,151	36.68
Total	**89,422**	**22,565**	**25.23**

Note: At the time of our review, Pennsylvania was not preparing reports showing value of prescription cancellations.

Table IV.4: Tennessee Prospective DUR System Warnings and Cancellations for the Period May 1, 1993, to October 31, 1993

Total claims processed	4,659,263
Total cost of claims processed	$103,821,733

	Total claims reversed	Value of reversals
Drug therapy alerts		
Drug-drug interactions	6,263	$198,507
Pregnancy conflict	299	2,683
Therapeutic duplication	5,716	244,625
Underutilization	1,684	45,937
Excessive daily dose	6,312	158,571
Excessive daily dose over age 65	319	19,755
Excessive daily dose children	154	2,654
Excessive quantity dispensed	3,194	238,772
Insufficient daily dose over age 65	1,641	16,239
Drug-disease interaction	242	4,983
Total	25,824	932,726
Early refills denied	108,456	3,106,450
Total claims reversed/value	**134,280**	**$4,039,176**
Reversals/value of reversals as a percent	2.88	3.89

Status of State Implementation of Prospective DUR Systems

States Operating Systems as of December 31, 1993

State	Date operations began
Illinois	January 1993
Maryland	January 1993
New Mexico	October 1993
Missouri	February 1993
Pennsylvania	June 1993
Tennessee	April 1993
Vermont	November 1993
West Virginia	July 1992

States Planning to Implement Systems

State	Date operation planned to begin
Alabama	Date not set
Arkansas	Date not set
California	1994
Colorado	1994
Connecticut	1995
Delaware	1994
District of Columbia	1994
Florida	1994
Indiana	1994
Idaho	1995
Iowa	1994
Kentucky	1994
Maine	1994
Minnesota	1994
Nebraska	Date not set
New Hampshire	1994
New Jersey	1995
New York	1994
Oklahoma	1994
Oregon	1994
Texas	1994
Utah	1994
Virginia	1994

States Not Planning to Implement Systems

State
Alaska
Arizona[a]
Georgia
Hawaii[a]
Mississippi
Montana
Nevada[a]
North Carolina
North Dakota
Ohio
Rhode Island
South Carolina
South Dakota
Washington[a]
Wisconsin
Wyoming

[a]These states do not plan to acquire automated prospective DUR systems because most of their Medicaid patients will be covered under some type of a health maintenance organization plan. The Social Security Act does not require states to conduct drug utilization reviews for covered outpatient drugs that are dispensed by health maintenance organizations.

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUL 19 1994

Mr. Gene L. Dodaro
Assistant Comptroller General
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Dodaro:

Enclosed are the Department's comments on your draft report, "Prescription Drugs: Automated Prospective Review Systems Offer Significant Potential Benefits for Medicaid." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

June Gibbs Brown
Inspector General

Enclosure

Comments of the Department of Health and Human Services
on the General Accounting Office (GAO) Draft Report,
"Prescription Drugs: Automated Prospective Review Systems
Offer Significant Potential Benefits for Medicaid"

The GAO concedes that data is not yet available to conclusively show the benefits and costs of using Statewide automated drug utilization review (DUR) systems for Medicaid prescriptions. However, GAO believes that these systems offer a tremendous opportunity to improve patient safety. As a result, although not statutorily required, GAO reports that all States should consider the use of Statewide automated prospective DUR systems for the Medicaid program or for any other Federal program providing a prescribed drug benefit. To aid them in considering these systems, GAO believes the States need additional information about system use and benefits. In addition, GAO believes all States could benefit from Federal system guidance to help ensure implementation of effective systems.

We agree with GAO's findings. It is our view that the rapid movement by States to adopt this technology, documented in the GAO report and in a survey conducted in 1993 by the Health Care Financing Administration (HCFA), testifies to State Medicaid agency recognition of the value of these systems.

While we generally agree with GAO's recommendations, we have not provided information to the States documenting the cost-effectiveness of these systems because we believe that work adequately documenting this has not appeared in the research literature. HCFA has contracted for the development of methodological guidance on how to evaluate the cost-effectiveness of conducting prospective DUR through electronic systems and will distribute this report to all Medicaid programs when it becomes available.

In addition, we expect to receive shortly, as required by section 1927(g)(3)(D) of the Social Security Act, an annual report from each State on their DUR programs. We expect that these reports will provide us with better information on the experience of States with on-line prospective DUR and other aspects of the DUR program mandated by OBRA 1990. We plan to share our analysis of these reports with all States as soon as possible. In our view, these efforts will implement the recommendations contained in GAO's report.

Major Contributors to This Report

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Medicaid Drug Fraud: Federal Leadership Needed to Reduce Program Vulnerabilities (GAO/HRD-93-118, Aug. 2, 1993).

Medicaid Prescription Drug Diversion: A Major Problem, But State Approaches Offer Some Promise (GAO/T-HRD-92-48, July 29, 1992).

Prescription Drug Monitoring: States Can Readily Identify Illegal Sales and Use of Controlled Substances (GAO/HRD-92-115, July 21, 1992).

Prescription Drugs: HCFA's Proposed Drug Utilization Review System Ignores Quality of Care Issues (GAO/PEMD-89-26BR, July 13, 1989).

Prescription Drugs: Information on Selected Drug Utilization Review Systems (GAO/PEMD-89-18, May 24, 1989).

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