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Report to Congressional Requesters

June 1996

PRESCRIPTION DRUGS AND MEDICAID

Automated Review Systems Can Help Promote Safety, Save Money

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GAO

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Accounting and Information
Management Division

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June 11, 1996

The Honorable William F. Clinger, Jr.
Chairman
Committee on Government Reform and Oversight
House of Representatives

The Honorable Christopher Shays
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Reform and Oversight
House of Representatives

The Honorable Edolphus Towns
Ranking Democratic Member
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Reform and Oversight
House of Representatives

It is widely accepted in the health care community that inappropriate use of prescription drugs can cause adverse reactions that can lead to drug-induced illness, hospitalization, even death. Such inappropriate use can also be expensive for the Medicaid program. Concerned about this issue, the Congress mandated that states establish utilization review programs to review Medicaid prescriptions before drugs are dispensed (called prospective reviews) in order to prevent potential adverse medical reactions. The legislation did not require that prospective screening be automated. However, 43 states plus the District of Columbia have implemented or plan to implement automated prospective drug utilization review (PRODUR) systems. In most instances, PRODUR systems are implemented concurrently with an automated screening capability for Medicaid eligibility since both depend on automated systems that offer real-time responses to inquiries. The five states in our review have this feature.

In August 1994 we reported on the potential benefits to the Medicaid program of automated PRODUR systems, after examining how information technology could be used in implementing a drug utilization review (DUR)

program.[1] In response to your request, this report examines states' actual experiences in using automated PRODUR systems in their Medicaid programs, recognizing that such experience has been brief. Specifically, you asked that we focus on how such systems can (1) improve patient safety by identifying and preventing inappropriate drug therapy, (2) reduce program costs, and (3) reduce the incidence of fraud, waste, and abuse. You also asked that we determine any other concerns that would hinder the effective implementation of these systems. Finally, we discuss the varying ways in which these systems can be established, and the role that the Department of Health and Human Services' (HHS) Health Care Financing Administration (HCFA) and others could play in enhancing states' effective use of PRODUR systems.

Results in Brief

Automated prospective drug utilization review (PRODUR) systems increased patient safety and reduced Medicaid program costs in the five states whose systems we examined; all five states found the systems beneficial and worthwhile. During a 12-month period ending June 30, 1995, these five states' systems alerted pharmacists to over 6.3 million prescriptions that had the potential to cause adverse medical reactions from drug therapy problems including drug-drug interaction, overutilization, and pregnancy conflict.[2] Over 650,000 (10 percent) of these prescriptions were canceled because of the potential serious risk to patients. According to state officials, pharmacists reviewed and eventually filled the other prescriptions on the basis of the pharmacists' professional judgment and/or consultation with the recipients or their physicians.

Along with increasing patient safety, these systems also reduced program costs by over $30 million, according to state and contractor reports. Over $5 million of this total was attributable to rejecting efforts to refill prescriptions before a large portion of the earlier prescription would have been consumed, potentially causing harm to the patient; the remaining $25 million resulted from prescriptions that were denied due to patient ineligibility. While these direct benefits are significant, the major dollar savings, in all likelihood—though more difficult to document—are achieved through avoided hospitalization due to inappropriate drug therapy. On the basis of its review of studies related to drug-induced illnesses, the Food and Drug Administration (FDA) indicated that 6.4 percent of hospital admissions nationwide can be traced to inappropriate

[1]Prescription Drugs: Automated Prospective Review Systems Offer Potential Benefits for Medicaid (GAO/AIMD-94-130, Aug. 5, 1994).

[2]New Mexico's alert data cover only the 6 months between January and June 1995.

drug therapy; some studies cite even higher rates for the elderly. Accordingly, avoided hospitalization could potentially save hundreds of millions of dollars annually. Savings could also accrue because PRODUR systems can help identify potential fraud, waste, and abuse.

The five states in our sample screened for different conditions and handled prescription cancellations differently. Consequently, reported numbers and types of patient safety alerts, prescription cancellations, and rates of savings varied. One state, for example, did not screen for pregnancy conflict. Three states automatically deny prescriptions with overutilization alerts, while the other two states place the responsibility with pharmacists to either deny or fill the prescriptions following such alerts. At present, states have no systematic way to share experiences and best practices. One approach toward accomplishing this would entail establishing a central clearinghouse at the state or federal level to collect and disseminate information. This would allow all states to make more informed decisions, offering citizens the best protection and states the most savings.

Background

Authorized in 1965 under Title XIX of the Social Security Act, Medicaid is a federally aided, state-run medical assistance program. Over 35 million people received an estimated $152 billion in Medicaid services during fiscal year 1995. 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 and physician care, under their Medicaid programs. Federal regulations also authorize states to provide optional services, such as optometrist services, eyeglasses, and prescription drugs. During fiscal year 1995, all states provided prescription drugs as part of their Medicaid programs; the reported cost of these drugs during that year was about $8.3 billion.

Because of growing concern over the increased use and cost of prescription drugs, in 1990 the Congress amended the Social Security Act to require states to implement DUR programs by January 1, 1993.[3] The legislation mandated that these reviews include prospective screening for potential drug problems due to therapeutic duplication, drug-disease contraindication, drug-drug interaction, incorrect drug dosage, incorrect

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

duration of treatment, drug-allergy interactions, and clinical abuse or misuse. (A glossary of drug utilization review terms appears at the end of this report.) HCFA was instructed to issue guidelines to the states on prospective DUR cost and benefit reporting. While not requiring that states use automated systems for prospective screening, the law encouraged their use, and required HCFA to initiate at least 10 statewide automated PRODUR demonstration projects. HCFA was required to report to the Congress by January 1, 1994.

In addition to promoting patient safety, DUR programs must also be designed to educate physicians and pharmacists to better identify patterns of fraud, abuse (including overuse), or other inappropriate or medically unnecessary care. Physicians and pharmacists can also use these systems to increase their knowledge about patterns of use associated with specific drugs or groups of drugs.

How the Automated System Works

When a Medicaid patient submits a prescription to be filled, the pharmacist transmits recipient identification and prescription information to a statewide database via the PRODUR system.[4] In an on-line, real-time environment, after verifying the recipient's eligibility, the system screens the prescription against the recipient's known Medicaid medical and prescription history. The system then sends the pharmacy a message indicating whether the claim is "payable" (valid), and whether any potential drug therapy problem, such as a drug-drug interaction, exists.

If a potential drug therapy problem does exist, the pharmacist consults with the recipient and/or the recipient's physician, depending upon the seriousness of the problem. After such consultation and according to the pharmacist's judgment, the pharmacist may fill the prescription, resubmit the claim for a different drug prescribed by the physician, or submit a reversal to cancel the claim.

Pharmacies in states that do not use automated, statewide PRODUR systems are generally limited to comparing the prescription presented with the patient's medical history and prescription data maintained at that specific pharmacy or chain of pharmacies. Such a local system would not have the benefit of the patient's complete Medicaid history; moreover, a local system would lack on-line eligibility verification.

[4]Each state's PRODUR system is integrated with its Medicaid Management Information System (MMIS), used by the state to process Medicaid claims; each MMIS includes a statewide database of patients' drug and medical histories.

Scope and Methodology

To determine if states' PRODUR systems have improved patient safety, we obtained contractor-prepared reports and other data for five of the eight states that had been operating automated PRODUR systems for 12 months or longer at the time we began our review in May 1995: Maryland, Missouri, New Mexico, Oregon, and Pennsylvania.[5] These reports showed the number and types of drug therapy "alerts" transmitted by each state's PRODUR system, along with the number of claims pharmacies reversed as a result of such alerts. We selected these five states because (1) a single contractor serviced three of the states (Maryland, New Mexico, and Oregon) and agreed to perform the needed analyses, and (2) two states (Missouri and Pennsylvania) agreed to provide us with 12 months' worth of their Medicaid prescription drug data for our own analysis.

To determine the extent to which states' PRODUR systems have provided measurable savings, we and contractors analyzed the five states' PRODUR data for all conditions screened for. To determine actual savings realized from the denial of overutilization claims (often called "early refills"[6]), we analyzed all such transactions denied between July 1, 1994, and March 31, 1995, identifying whether they were subsequently refilled within 90 days—including the period April 1995 through June 1995.[7] State PRODUR and HCFA officials agreed with our assumption that if the prescriptions were not refilled within 90 days after being initially presented, they probably would not be refilled, and that the value of these prescriptions could reasonably be viewed as measurable savings.

To evaluate the extent to which on-line eligibility-verification screening provided tangible savings, we identified the number of prescriptions denied (and the dollar value of the drugs) because recipients were not eligible for Medicaid benefits on the day they submitted their prescriptions. Eligibility screening is performed by a system separate from but often utilized with PRODUR systems. In addition, our estimates of cost savings derived from avoided hospitalization are based on FDA data.

[5]Two of the states included in our earlier review (see GAO/AIMD-94-130, Aug. 5, 1994)—Tennessee and West Virginia—were not included in this review because of data-availability problems. Therefore, two other states—New Mexico and Oregon—were added to Maryland, Missouri, and Pennsylvania.

[6]Early refills include prescriptions submitted for the same drug, for the same person, and/or by the same or a different pharmacy before a predetermined amount of the original prescription—such as 75 percent—would theoretically have been consumed by taking the dosage as prescribed.

[7]For New Mexico, early-refill transactions between January 1 and September 30 were analyzed—including whether any prescriptions initially denied were filled within the following 90 days, through December 31, 1994.

To discern the degree to which PRODUR systems can assist in identifying potential fraud, waste, and abuse, we reviewed alerts for overutilization (early refill) and therapeutic duplication; in such cases, individuals may be trying to obtain for resale a greater quantity of medication than that prescribed.

We performed our review from May 1995 through April 1996, in accordance with generally accepted government auditing standards except that, as agreed with the requesters, we did not independently verify the accuracy of state- and contractor-provided prescription-transaction data. This was due to the excessive amount of time that would have been required to (1) obtain specific prescription information (such as physician and pharmacy names) and (2) trace these data back to the original prescription documents. Accordingly, we cannot verify the accuracy of the information provided. Our conclusions regarding patient safety and program savings are based on these data. HHS provided written comments on a draft copy of this report; they are reprinted as appendix I.

State Data Suggest That Automated Statewide Systems Enhance Patient Safety

Data from PRODUR systems operated by five geographically diverse states—Maryland, Missouri, New Mexico, Oregon, and Pennsylvania—show inappropriate drug therapy to be an ongoing and serious problem in the Medicaid program. These systems reported screening over 31.7 million prescription drug claims during 12-month periods between January 1994 and June 1995, and sent pharmacists alerts of potentially inappropriate drug therapy for about 6.3 million (20 percent) of these claims. Over 650,000 of these claims (2 percent of the total) were reported canceled because of serious risks posed by such conditions as potential drug-drug interaction, drug-disease conflict, and pregnancy conflict.

Table 1 shows the potential for adverse medical reactions, as evidenced by the fact that alerts for drug-drug interaction, overutilization, and therapeutic duplication occur in great numbers. (Appendix II contains detailed data on PRODUR operations for each of the five states reviewed.)

Table 1: Types of Warnings and Number of Prescriptions Identified in Five States as Potentially Causing Adverse Medical Reactions

Rounded to nearest thousand

Type of warning	Number of prescriptions
Overutilization	1,619,000
Therapeutic duplication	1,491,000
Drug-drug interaction	752,000
Underutilization	403,000[a]
Drug-disease interaction	398,000[b]
Pregnancy alert	15,000[b]
Others[c]	1,692,000
Total	**6,370,000**

[a]Total represents activity in four states, since one state does not screen for this condition.

[b]Total represents activity in three states, since two states do not screen for this condition.

[c]Includes other warnings such as excessive daily dose—see appendix II for more detailed information on the types of warnings issued by individual states' systems.

Source: State data, which we did not independently verify.

Program Costs Can Be Significantly Reduced

Along with increasing patient safety, the PRODUR systems in the states we reviewed reduced Medicaid program costs by millions of dollars annually through the cancellation of potentially wasteful prescriptions and the denial of prescriptions to ineligible recipients. Experiences in the five states reviewed show that program savings can more than offset the cost of these relatively inexpensive systems. Further, however, to the extent that these systems also help prevent unnecessary hospitalization due to adverse medical reactions from prescribed drugs, actual annual cost savings (according to a 1995 FDA review) may be appreciable.

The cancellation of prescriptions due to the overutilization (early refill) alert has provided the five states in our review with substantial recurring savings. While a legitimate need for an early refill may exist in some situations, early refills can also indicate drug overutilization, which can threaten patient safety, or increase the potential for fraud or abuse. Our analyses showed that most canceled early refill prescriptions are subsequently filled, but savings from those not filled within 3 months, and thus presumed to represent program savings, have been substantial. As table 2 shows, states realized savings of about $5 million from canceled prescriptions not filled, with individual state savings ranging from about $153,000 to about $2.3 million.

Table 2: States' Cost Reductions From Prescription Cancellations Due to Overutilization (Early Refill) and Ineligibility

State	Overutilization denials[a]	Ineligibility denials	Total cost reductions	One-time installation costs
Maryland	$1,168,665	$4,532,395	$5,701,060	$165,000
Missouri	152,577	1,423,229	1,575,806	508,000
New Mexico	559,809	1,514,068	2,073,877	174,000
Oregon	2,252,043	1,532,566	3,784,609	360,000
Pennsylvania	765,124	16,637,789	17,402,913	675,000
Total	**$4,898,218**	**$25,640,047**	**$30,538,265**	**$1,882,000**

[a]Transactions for all states except New Mexico were analyzed for the period July 1994 through June 1995; this included analyzing whether denied prescriptions were refilled within 90 days, through June 1995. In the case of New Mexico, data cover January through December 1994, likewise including whether denied prescriptions were filled within 90 days, through December 1994.

Source: State data, which we did not independently verify.

The five states also realized substantial savings from PRODUR systems with companion on-line screening capabilities to ensure that recipients are eligible for Medicaid benefits at the time a prescription is presented. Without on-line eligibility verification, Medicaid recipients can continue to obtain benefits for up to a full month, even if they lose eligibility during the middle of the month. The annual savings from this function, reported at over $25 million for the five states, more than offset—by a considerable margin—each state's one-time system installation costs, which ranged from a reported $165,000 to $675,000.[8] For example, as shown in table 2, Pennsylvania's PRODUR system denied about $16.6 million in prescriptions because of ineligibility, from July 1994 through June 1995; in contrast, its one-time installation cost was $675,000.

On the basis of its review of studies related to drug-induced illnesses, FDA estimates that 6.4 percent of all hospital admissions nationally are caused by inappropriate drug therapy—5 percent due to patient noncompliance with drug regimens, such as overutilization, and an additional 1.4 percent due to adverse drug reactions. Numerous other studies have been conducted worldwide to determine the extent to which inappropriate drug therapy results in hospitalization, with estimates ranging from 3 percent for the general population to as high as 28 percent for the elderly.

[8]The states' one-time installation costs included the costs to add on-line eligibility-verification capabilities to their PRODUR systems. We were unable to compare before and after operating costs because data were not available indicating operating expenses before the installation of the PRODUR systems. Individual states' annual maintenance costs, we were told, run about $5,000 for updating the systems.

Considering that Medicaid's fiscal year 1995 inpatient hospitalizations totaled about $42 billion, even limited implementation of PRODUR systems could have a significant impact on reducing overall Medicaid program costs.

Potential Fraud and Abuse Can Be Identified and Prevented

As we have pointed out in past reports,[9] potential fraud and abuse in the Medicaid prescription drug program is a serious problem, with dollar losses widely estimated to be as high as 10 percent of total program costs. In 1992 we reported how 10 states had used retrospective drug monitoring programs to detect and deter the theft of controlled substances[10] within the Medicaid program.[11] However, our analysis of the five states' systems shows that automated PRODUR systems offer a much more cost-effective alternative to a "pay-and-chase" approach—in which only retrospective reviews are undertaken—by detecting potential fraud and abuse at the time a recipient submits a prescription, and by denying a potentially invalid claim before the drugs are dispensed.

The PRODUR systems' alerts for early refills and therapeutic duplication provide states with the tools needed to detect potential fraud and abuse and prevent them before they occur.[12] These alerts can be a clue to detecting potential fraud or abuse because an individual may be obtaining a greater quantity of medication than medically necessary, with intentions of selling the drugs—often at inflated street prices. For example, our analysis of one of the five states' data identified over 2,200 recipients who, during a 15-month period, each obtained a 20-months' supply or greater of controlled substances, such as Darvon and Valium, in the same therapeutic drug class. Further analysis of the 2,200 recipients showed that

- 180 of them went to 10 or more different physicians to obtain their prescriptions; 1 went to 108;

[9]Prescription Drug Monitoring: States Can Readily Identify Illegal Sales and Use of Controlled Substances (GAO/HRD-92-115, July 21, 1992) and Medicaid Drug Fraud: Federal Leadership Needed to Reduce Program Vulnerabilities (GAO/HRD-93-118, Aug. 2, 1993).

[10]Controlled substances are drugs or other substances that have the potential for abuse, where such abuse can lead to physical or psychological dependence. The Controlled Substance Act of 1970 (Public Law 91-513) places controlled substances into one of five classes (high to low) on the basis of their potential for abuse or dependence.

[11]GAO/HRD-92-115, July 21, 1992.

[12]Federal regulation (42 CFR 456.705) defines therapeutic duplication as the prescribing and dispensing of two or more drugs from the same therapeutic drug class such that the combined daily dose puts the recipient at risk of adverse medical result or incurs additional program costs without additional therapeutic benefit.

- 252 of the recipients obtained a 3-years' supply or greater of controlled substances; 6 of them obtained a 10-years' supply or greater; and
- 219 of the recipients obtained controlled drugs costing the Medicaid program $1,500 or more; 8 of the recipients obtained drugs costing $10,000 or more.

States Implement Systems Differently, Often Not Sharing Experiences

The states in our review have all implemented their automated PRODUR systems differently, in large part because no overall source of information or guidance for implementing PRODUR systems exists. Some states issue alerts for a greater number and variety of conditions relating to patient age, duration of prescription, and other medical conditions (see appendix III). Each state has its own DUR board, which independently sets screening criteria and policies.

Although all of the systems in the states we reviewed screen for drug-drug interaction, overutilization, and therapeutic duplication, we found significant differences in the types of drug therapy problems the states' PRODUR systems screen for. One state's system did not screen for pregnancy conflict, and two of the states' systems did not screen for underutilization (an indication of noncompliance with a prescribed drug regimen)—both problems that could have dramatic effects on patient safety. Underutilization data we obtained from three states show that patient noncompliance with drug-therapy instructions could be a significant problem in the Medicaid program. In Maryland alone, for example, between July 1994 and June 1995, over 300,000 underutilization alerts were sent.

State data also indicate that how alerts regarding early refill and therapeutic duplication claims are administered can affect savings, and the identification and prevention of potential fraud, waste, and abuse. As table 3 shows, one state—which does not automatically deny early refill claims but that requires the pharmacist to initiate such denials—had a total 9-month claims volume of about 5.8 million and about 6,100 early refill claims that were not later refilled, resulting in savings of about $153,000. In contrast, another state—which does automatically deny early refill claims—had a lesser total 9-month claims volume (about 3.2 million) but had about 30,000 early refill claims not later refilled, resulting in significantly more savings—about $1.2 million. Thus, it appears that automatic denial can offer a better chance at detecting prescriptions that could be dangerous, potentially fraudulent, or both.

Table 3: Rates of Prescription Cancellation for Two States, Pharmacist Denial v. Automatic Denial

	State 1: Pharmacist denial	State 2: Automatic denial
Total number of claims	5,836,000	3,162,000
Number initially canceled	21,000	146,000
Number remaining canceled after 90 days	6,100	30,000
Savings from canceled claims	$153,000	$1,200,000

Source: State data, which we did not independently verify.

Three of the states' systems automatically deny early refills; none automatically deny claims for therapeutic duplication. A fourth state, Maryland, is, however, considering changing its system to automatically deny claims for therapeutic duplication.

HCFA's Information Sharing Has Been Limited

As stated earlier, the Social Security Act, as amended by the Omnibus Budget Reconciliation Act of 1990, encourages states to use automated systems for prospective DUR, and requires HCFA to conduct demonstration projects of PRODUR systems and report project results to the Congress. HCFA is currently conducting a PRODUR demonstration project in cooperation with the state of Iowa and has provided project status reports to the Congress. No other demonstration projects are planned at this time.

Since the inception of the Iowa demonstration project in 1994, HCFA has provided annual reports for 1994 and 1995 to the Congress presenting the project goals and objectives, evaluation design, plans for collecting and analyzing data and reporting project results, and baseline data on Iowa's past Medicaid program expenditures and prescription volumes. The 1995 report,[13] transmitted to the Congress on March 1, 1996, stated that data are not yet available with which to evaluate the potential benefits of the Iowa PRODUR system. Reports planned for 1996 and 1997 are to begin to provide analyses of claims and eligibility data from Iowa, and a final evaluation report is to be prepared in 1998 after the project's scheduled conclusion in March of that year. As a result, the Iowa demonstration project will provide little information to the states and the District of Columbia as they implement their PRODUR systems. Among the 43 states plus the District of Columbia that plan to implement systems, 38 are scheduled to have theirs in place by the end of 1996.

[13]Medicaid Drug Use Review Demonstration Projects - Report to Congress 1995, Office of Research and Demonstrations, Health Care Financing Administration, U.S. Department of Health and Human Services.

In addition to HCFA's statutory responsibilities, in our 1994 report[14] we urged HCFA to gather information on the costs and benefits of automated review systems, develop guidance on features and capabilities, and make such information available to all states. HCFA has only partially responded to these recommendations. In August 1994 HCFA issued guidelines to assist the states in estimating and reporting the costs and benefits of both retrospective and prospective drug utilization review. However, according to HCFA officials, while they have gathered information on PRODUR programs from required annual reports submitted by the states, they have not developed "best practices" or disseminated what information they do have, due to a lack of resources. Further, HCFA officials state that they have no plans at this time to increase their role, since efforts to reform health care being discussed in the Congress may affect the ways in which the Medicaid program operates.

Conclusions

With automated PRODUR systems, most states are recognizing an opportunity to use low-cost technology to help both physicians and pharmacists safeguard Medicaid recipients from inappropriate drug therapy and its potential adverse medical reactions. While the primary emphasis of such systems—appropriately—has been safety, both safety benefits and dollar savings accrue from their use. Since results vary on the basis of how such systems are administered, it is important that states share their experiences. Absent any analysis of data from the Iowa demonstration project or any concerted effort by HCFA to collect and share other states' experiences, states have had only limited access to both safety and cost data—information that is critical to informed decisionmaking and to maximizing PRODUR system effectiveness and efficiency.

Recommendation

Given the substantial safety benefits that can accrue to Medicaid recipients and the strong potential for immediate savings to the Medicaid program through the effective use of automated PRODUR systems, we recommend that the Secretary of Health and Human Services direct the Administrator, Health Care Financing Administration, to actively facilitate state sharing of information on the most efficient use of PRODUR systems. One way would be to quickly help establish a working group or other such forum for coordinating the collecting and sharing of information on best practices for automated prospective drug utilization review programs, on a nationwide basis.

[14]GAO/AIMD-94-130, Aug. 5, 1994.

Agency Comments and Our Evaluation

In commenting on a draft of our report, the Department of Health and Human Services generally agreed with our recommendation and the facts presented. It stated that automated prospective drug utilization review systems are extremely beneficial in ensuring that prescriptions are medically necessary and unlikely to cause adverse drug reactions, and concurred with our recommendation that HCFA facilitate state information sharing on best practices for automated PRODUR programs. It noted several prior and ongoing initiatives related to this objective, including (1) the Office of Inspector General's May 1995 report[15] focusing on states' progress in implementing statutory DUR requirements, (2) participation in a project funded by the American Pharmaceutical Association to analyze PRODUR best practices,[16] (3) continuing participation in the annual American Drug Utilization Review Symposium, and (4) the gathering of information on states' best practices that HCFA plans to publish in its Drug Utilization Review Newsletter in June 1996. In connection with these activities, the Department noted that while resources are limited, it plans to continue and improve its role as a clearinghouse dedicated to collecting information and promoting the exchange of information among states on the operation of effective automated PRODUR systems.

We had reviewed the documents the Department referred to and agree that these efforts have provided some information to the states on the operation of effective automated PRODUR systems. The Department's future such efforts will need to provide an ongoing and continuous exchange of information as most states move rapidly toward operational PRODUR systems by the end of 1996. Information in the Inspector General's report and in the report resulting from the project funded by the American Pharmaceutical Association cited by the Department in its response is based on the states' early experiences with automated PRODUR systems—primarily 1993 data. And HCFA's stated plans to issue a DUR newsletter in June 1996 will be only the second newsletter since the states were required to implement DUR programs in January 1993.

While agreeing that PRODUR systems are often capable of deterring potentially fraudulent activity, the Department said the primary emphasis of these systems is on patient safety and quality of care. It stated that PRODUR systems are not specifically designed to detect Medicaid fraud and

[15]Medicaid Drug Use Review Programs: Lessons Learned by States, Office of Inspector General, Department of Health and Human Services, OEI-01-92-00800, May 1995.

[16]Medicaid DUR Programs: 1993 Final Report to American Pharmaceutical Association Foundation, Earlene E. Lipowski, R.Ph., Ph.D., College of Pharmacy, University of Florida; and Ted Collins, R.Ph., Center for Health Systems Research and Analysis, University of Wisconsin-Madison, August 1995.

abuse and that retrospective DUR systems may be more capable of detecting potentially fraudulent activity and referring this activity to states' Medicaid Surveillance Utilization Review units for follow-up. While we acknowledge the safety and quality-of-care orientation, it is being clearly established in states with automated PRODUR systems that tremendous benefits accrue for program integrity—detecting and preventing potentially fraudulent or abusive activity before drugs are dispensed. Relying on retrospective systems alone is needlessly restrictive and expensive, resulting in a "pay-and-chase" approach in which recipients have already received the drugs and the states' Medicaid Surveillance Utilization Review units must use their resources to conduct investigations and seek whatever recovery they can attain—usually minimal.

Finally, the Department recommended caution in attributing the $30 million in cost savings cited in our report to denials due to early refills and ineligibility, and noted that additional methodological issues should be considered. We discussed these issues with HCFA program managers responsible for DUR program implementation. They said that our methodology could overstate savings because our early refill analysis searched for 90 days after an initial denial to see whether a prescription was subsequently filled, while states can allow recipients to get up to a 100-days' supply of drugs. HCFA stated that with 100-day-supply prescriptions, situations could arise in which more than 90 days would elapse between an initial denial and a subsequent refill, thus eroding program savings identified under our methodology.

While such situations could occur, they appear unlikely because of the series of events that would be involved, that is, a recipient's seeking to refill a 100-day-supply prescription several days after initially filling it, being denied, then waiting over 90 days before attempting a refill. Moreover, further analysis of the data obtained for two of the states in our review showed that only about 1 percent of their total prescription drug claims were for prescriptions with over a 90-days' supply. In reference to cost savings attributed to ineligibility, HCFA described a specific example in which recipients under states' medically needy programs may not become eligible for Medicaid benefits until certain portions of their incomes are spent on medical expenses. Thus, some ineligible recipients denied prescriptions may subsequently obtain these prescriptions after they become eligible. Our methodology did not consider ineligible recipients' later becoming eligible and obtaining previously denied prescriptions. However, this possibility assumes that ineligible recipients would postpone filling denied prescriptions until after they become eligible for

Medicaid benefits. Further, HCFA's example involves those receiving benefits under states' "medically needy"[17] programs—recipients that accounted for only about 11 percent of the total Medicaid population during fiscal year 1994—the latest data available.

We are sending copies of this report to the Secretary of Health and Human Services; the Administrator, Health Care Financing Administration; the Director, Office of Management and Budget; and other interested parties. Copies will also be made available to others upon request.

We plan no further distribution of this report until 15 days after the date of this letter, unless you publicly announce its contents earlier. At that time, we will release copies to interested parties.

Please contact me at (202) 512-5539 if you have any questions concerning this report. Major contributors to this report are listed in appendix V.

Patricia T. Taylor
Director, Health, Education, and
Human Services Information Systems

[17]The term "medically needy" is defined differently by each state, but in general applies to those whose incomes are too high to qualify for Medicaid but are nonetheless in need of assistance. In one state, for example, those whose incomes are too high for unqualified Medicaid assistance but fall within 133 percent of the poverty level can receive Medicaid benefits after spending a specified amount for medical services during the fiscal year.

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Abbreviations

CFR	code of federal regulations
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 System
PRODUR	prospective drug utilization review
R_x	prescription

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

APR 29 1996

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 and Medicaid: Automated Review Systems Can Help Promote Safety, Save Money." 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,

June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Comments of the Department of Health and Human Services on the General Accounting Office (GAO) Draft Report, "Prescription Drugs and Medicaid: Automated Review Systems Can Help Promote Safety, Save Money"

We agree that automated prospective drug utilization review (DUR) systems are extremely beneficial in ensuring that prescriptions are medically necessary and unlikely to cause adverse drug reactions. We concur with the GAO's recommendation that the Health Care Financing Administration (HCFA) facilitate state information sharing on best practices for automated prospective DUR programs and have several initiatives underway in connection with this objective. We have gathered information from states that have implemented automated prospective DUR programs to determine, in detail, best practices of effective prospective DUR system design and operations. These will be published in the next edition of the HCFA DUR Newsletter. For your information, the Office of Inspector General issued a final report in May 1995 that focuses on progress made by states in implementating Omnibus Budget Reconciliation Act 1990 DUR requirements. (A copy of the report was provided to GAO staff.) We have also participated in a project funded by the American Pharmaceutical Association to analyze the DUR annual reports to determine best practices for both the automated prospective DUR and retrospective DUR programs. Finally, we will continue our participation in the annual American Drug Utilization Review Symposium, where states exchange information regarding the best practices in designing and operating prospective DUR systems. Although resources are limited, we plan to continue and improve our role as a "clearinghouse" dedicated to collecting information and promoting the exchange of information among states on the operation of effective automated prospective DUR systems.

While we agree that automated prospective DUR systems are often capable of deterring potential fraudulent activity through the "overutilization" or "early refill" alert, we would note that these programs are not designed specifically to detect Medicaid fraud and abuse. The emphasis of the prospective DUR program is on patient safety and quality of care. In fact, the retrospective DUR systems may be more capable of detecting fraudulent activity and referring this activity to Medicaid Surveillance Utilization Review units for follow-up.

We would also recommend caution in attributing $30 million cost savings to denials due to early refills and ineligibility. We believe there are several methodological issues to be considered in this regard, and would be pleased to discuss these issues with GAO.

We appreciate the opportunity to comment on this report and look forward to implementing the GAO recommendation.

Alerts and Claim Cancellations Resulting From States' PRODUR Systems

The following tables provide detailed contractor- and state-provided data on the results of automated PRODUR systems during 1994 and 1995. These data, which we did not independently verify, include (1) the number and cost of claims processed, (2) the types and numbers of drug therapy alert messages sent via the states' PRODUR systems, (3) the number of **overutilization/early refill prescriptions** denied and not later filled (highlighted in **bold** in each table), and (4) the number of claims canceled.

Tables for Missouri and Pennsylvania also include data on numbers of claims canceled for each drug therapy alert condition; similar data were not available for the other three states.

Table II.1: Maryland's PRODUR System Alerts and Cancellations, July 1, 1994 Through June 30, 1995

Total number of claims processed	**4,270,169**
Total cost of claims processed	**$136,708,110**
Drug therapy alert condition	**Number of alerts**
Drug-age conflict	10,193
Drug-disease interaction	28,782
Drug-drug interaction	182,164
Excessive daily dose	66,762
Excessive daily dose/children	696
Excessive daily dose/over age 65	22,373
Excessive quantity dispensed	15,289
Insufficient daily dose for age	12,134
Overutilization (early refill)	187,505
Pregnancy conflict	3,657
Therapeutic duplication	143,062
Underutilization	339,937
Total number of alerts	**1,012,554**
Total number of claims canceled due to alerts	**182,681**

Source: State data, which we did not independently verify.

Table II.2: Missouri's PRODUR System Alerts and Cancellations, July 1, 1994 Through June 30, 1995

Total number of claims processed		**6,780,901**
Total cost of claims processed		**$173,370,503**
Drug therapy alert condition	**Number of alerts**	**Number of claims canceled**
Above maximum daily dose	250,415	12,187
Above maximum dose range	17,934	690
Additive side effect	2,566	66
Below minimum daily dose	240,336	9,827
Below minimum dose range	36,515	1,328
Current R_x applies to 90-day therapy	39,868	1,177
Current R_x exceeds 90-day therapy	78,775	1,573
Current R_x initiates 90-day therapy	22,401	688
Drug-disease interaction	14,825	738
Drug-drug interaction	108,940	3,441
Drug-indicated disease conflict	59,052	2,411
Indicated for prior drug's side effect	831	13
Maintenance dose	17,993	209
Overutilization (early refill)	394,795	25,409
Side effect medical condition	823	10
Significant side effect	14,008	247
Therapeutic duplication	157,615	6,970
Total number of alerts		**1,457,692**
Total number of claims canceled due to alerts		**66,984**

Source: State data, which we did not independently verify.

Table II.3: New Mexico's PRODUR System Alerts and Cancellations, January 1, 1995 Through June 30, 1995

Total number of claims processed	**1,084,912**
Total cost of claims processed	**$26,286,725**
Drug therapy alert condition	**Number of alerts**
Drug-age conflict	16,609
Drug-disease interaction	23,008
Drug-drug interaction	38,373
Excessive daily dose	8,508
Excessive daily dose/children	1,974
Excessive daily dose/over age 65	7,148
Excessive quantity dispensed	1,273
Insufficient daily dose for age	56,349
Overutilization (early refill)	45,526
Pregnancy conflict	3,641
Therapeutic duplication	11,905
Underutilization	18,364
Total number of alerts	**232,678**
Total number of claims canceled due to alerts	**5,397**

Note: New Mexico changed contractors in January 1995; prior alert data are not available.

Source: State data, which we did not independently verify.

Table II.4: Oregon's PRODUR System Alerts and Cancellations, July 1, 1994 Through June 30, 1995

Total number of claims processed	**2,584,672**
Total cost of claims processed	**$74,767,962**
Drug therapy alert condition	**Number of alerts**
Drug-age conflict	8,668
Drug-disease interaction	40,451
Drug-drug interaction	223,665
Excessive daily dose	64,238
Excessive daily dose/children	694
Excessive daily dose/over age 65	19,744
Excessive quantity dispensed	5,439
Insufficient daily dose for age	11,765
Overutilization (early refill)	309,081
Pregnancy conflict	6,887
Therapeutic duplication	196,014
Underutilization	25,367
Total number of alerts	**912,013**
Total number of claims canceled due to alerts	**23,810**

Source: State data, which we did not independently verify.

Table II.5: Pennsylvania's PRODUR System Alerts and Cancellations, July 1, 1994 Through June 30, 1995

Total number of claims processed		**16,590,943**
Total cost of claims processed		**$503,963,506**
Drug therapy alert condition	**Number of alerts sent**	**Number of claims canceled**
Drug-age conflict	2,004	172
Drug-drug interaction	198,905	13,799
High dose alert	348,991	36,134
Low dose alert	539,836	36,121
Overutilization (early refill)	682,276	205,256
Pregnancy conflict	451	41
Therapeutic duplication	982,852	84,078
Total number of alerts		**2,755,315**
Total number of claims canceled due to alerts		**375,601**

Source: State data, which we did not independently verify.

Drug Therapy Problems Screened for by States' PRODUR Systems

Drug therapy alert condition	Maryland	Missouri	New Mexico	Oregon	Pennsylvania
Above maximum dose range		X			
Additive Side Effect		X			
Below minimum dose range		X			X
Current R_x applies to 90-day therapy		X			
Current R_x exceeds 90 day-therapy		X			
Current R_x Initiates 90-day therapy		X			
Drug-age conflict	X		X	X	X
Drug-disease interaction	X	X	X	X	
Drug-drug interaction	X	X	X	X	X
Drug-indicated disease conflict		X			
Excessive daily dose	X	X	X	X	X
Excessive daily dose/children	X		X	X	
Excessive daily dose/over age 65	X		X	X	
Excessive quantity dispensed	X		X	X	
Indicated for prior drug's side effect		X			
Insufficient daily dose for age	X		X	X	
Maintenance dose		X			
Overutilization/ early refill	X	X	X	X	X
Pregnancy conflict	X		X	X	X
Side effect medical condition		X			

(continued)

Drug therapy alert condition	Maryland	Missouri	New Mexico	Oregon	Pennsylvania
Significant side effect		X			
Therapeutic duplication	X	X	X	X	X
Underutilization	X		X	X	

Source: State data, which we did not independently verify.

State Implementation of PRODUR Systems: Status as of April 1, 1996

Figure IV.1: Nationwide View

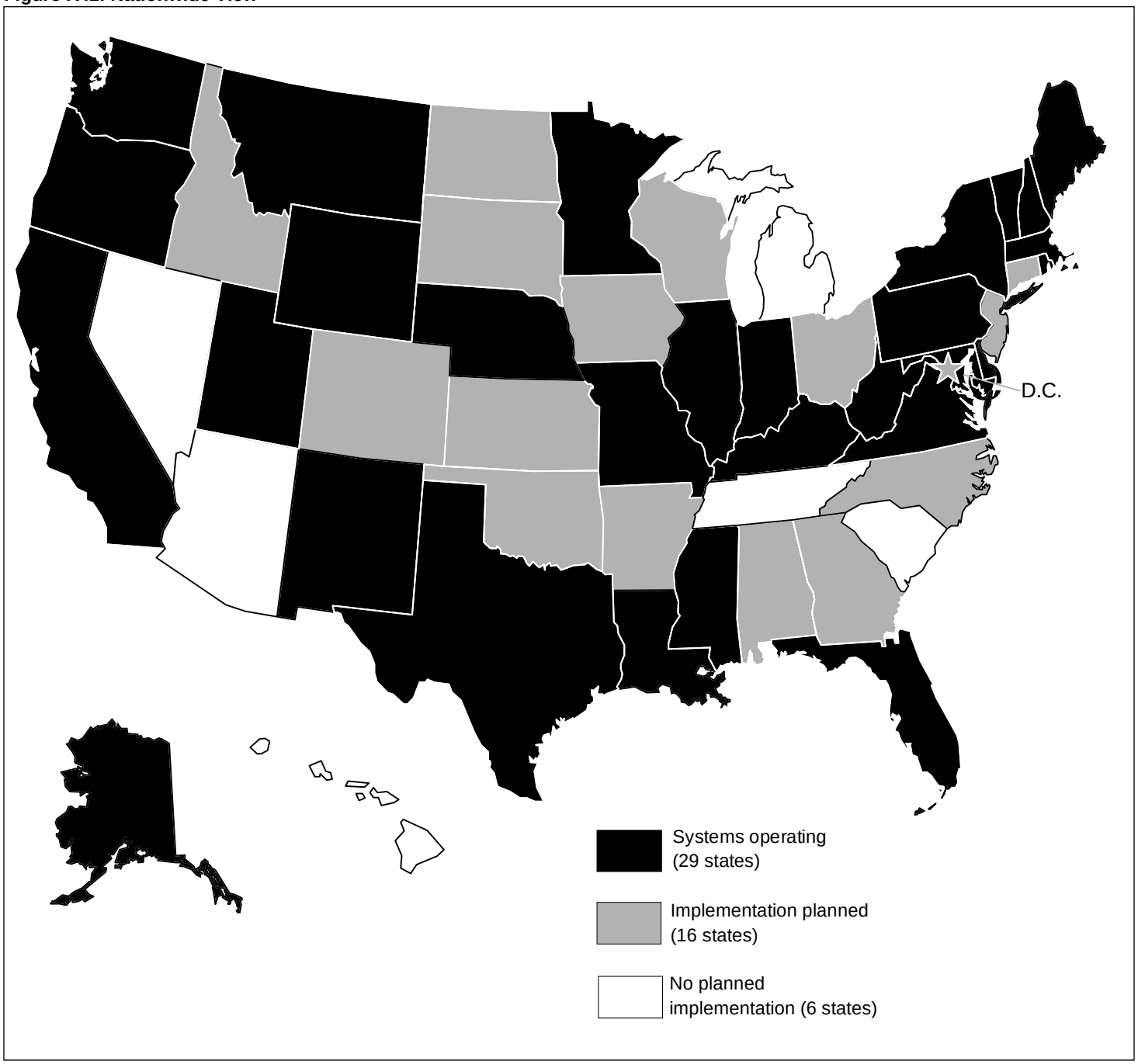

Table IV.1: Twenty-nine States Operating PRODUR Systems as of April 1, 1996, and Dates Begun

State	Date operation began
Alaska	June 1995
California	August 1995
Delaware	August 1994
Florida	July 1995
Illinois	January 1993
Indiana	March 1996
Kentucky	September 1994
Louisiana	April 1996
Maine	August 1995
Maryland	January 1993
Massachusetts	October 1995
Minnesota	February 1996
Mississippi	October 1995
Missouri	February 1993
Montana	September 1994
Nebraska	June 1995
New Hampshire	August 1995
New Mexico	October 1993
New York	March 1995
Oregon	March 1994
Pennsylvania	June 1993
Rhode Island	December 1994
Texas	March 1995
Utah	April 1995
Vermont	November 1993
Virginia	July 1994
Washington	March 1996
West Virginia	July 1992
Wyoming	October 1995

Table IV.2: Sixteen States Planning to Implement PRODUR Systems, as of April 1, 1996, and Planned Start Dates

State	Planned start
Alabama	1996
Arkansas	1997
Colorado	1996
Connecticut	1996
District of Columbia	1996
Georgia	1996
Idaho	1997
Iowa	1996
Kansas	1996
New Jersey	date not set
North Carolina	1996
North Dakota	1996
Ohio	1996
Oklahoma	1996
South Dakota	date not set
Wisconsin	1997

Table IV.3: Six States Not Planning to Implement PRODUR Systems

State
Arizona[a]
Hawaii
Michigan
Nevada
South Carolina
Tennessee[a]

[a]These states are exempt from the 1990 Social Security Act mandate to implement DUR programs because they operate managed care programs.

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Glossary

	Definitions of the following drug utilization review terms are from 42 CFR 456.702/705 and state PRODUR manuals.
Adverse Drug-Drug Interaction	The potential for, or the occurrence of, an adverse medical effect as a result of the recipient's using two or more drugs together.
Adverse Medical Result	A significant undesirable effect experienced by a patient due to the prescribed course of drug therapy.
Drug-Age Contraindication	Use of a drug that is not recommended for use in the age group of the patient. This can occur when the patient is too old or too young for the given medication.
Drug-Allergy Interaction	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 of an existing disease condition—such as an ulcer drug exacerbating a patient's high blood pressure.
Gross Overuse	Repetitive overutilization without therapeutic benefit.
Incorrect Drug Dosage	A dosage lying outside the standard daily dosage range necessary to achieve therapeutic benefit.
Incorrect Duration of Drug Treatment	The number of days of prescribed therapy exceeding or falling short of the standard recommendation for the condition for which it was prescribed.
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 the prescribed drug is not recommended during pregnancy.

Therapeutic Duplication	The prescribing and dispensing of two or more drugs from the same therapeutic class, such as analgesics (pain relievers), resulting in a combined daily dose that puts the recipient at risk of an adverse medical result, or that incurs additional program cost without additional therapeutic benefit.
Underutilization	Use of a drug in insufficient quantity to achieve a desired therapeutic goal.

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