United States General Accounting Office

139212

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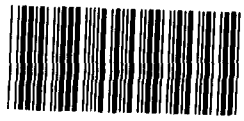
Testimony



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For Release
on Delivery
Expected at
9:30 a.m.
Tuesday,
August 1, 1989

Drug Utilization Review Under Medicare

Statement of
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Before the
Subcommittee on Human Affairs
Select Committee on Aging
House of Representatives

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Mr. Chairman and Members of the Committee:

It is a pleasure to be here today to share the results of our work on the proposed Health Care Financing Administration (HCFA) drug utilization review system. As reported in our recently released study, we examined three broad areas: drug safety, development and implementation of HCFA's proposed system, and pharmacy participation.[1]

Before turning to the results of our study, however, I think it is important to describe its context. As you are well aware, most elderly individuals find prescription drugs, as well as over-the-counter drugs, to be an important component of their health care. In addition to using, on average, a larger number of drugs than the general population, the elderly often take the drugs for longer periods.[2] Increases in medication increase the possibility of adverse drug reactions and/or drug interactions.[3] For example, a recent study by the Food and Drug Administration stated that

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

[2]P.P. Lamy, "Polymedicine and the Elderly," The Maryland Pharmacist, 63 (1987), pp. 12-15.

[3]J. Williamson and J.M. Chopin, "Adverse Reactions to Prescribed Drugs in the Elderly: A Multi-Center Investigation," Age and Aging, 9 (1980), pp. 73-80.

they had received 16 reports of adverse drug reaction for every 100,000 elderly patients--that is, those aged 65 or older--compared to 7 reports per 100,000 for the population under age 65.[4]

Because the elderly often have several chronic conditions that necessitate the use of multiple drugs for longer periods, they are at higher risk for drug-to-drug interactions due to unnecessary, incorrect, or excessive use of medication--including practices such as the use of a drug when it is not medically indicated, use of several drugs when one would suffice, and concurrent use of drugs that can result in a drug interaction.

Current research on prescription practices for the elderly clearly indicates that inappropriate drug prescription can cause adverse drug reactions, which can lead to drug-induced illness, hospitalization, and even death--in addition to enormously wasteful expenditures by the government, private insurance companies and, of course, the recipients of these prescriptions themselves. According to a recent study by the Public Citizen Health Group, each year there are approximately 61,000 older adults with drug-induced Parkinsonism, 32,000 with hip fractures attributable to drug-induced falls, 163,000 with drug-induced or worsened memory loss or impaired thinking, and 243,000 hospitalized because of

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[4]L.A. Tanner et al., "Spontaneous Adverse Reaction Reporting in the Elderly for 1986," Journal of Geriatric Drug Therapy, 3 (1989), pp. 31-54.

adverse drug reactions.[5] The economic and human costs of drug-induced illness are significant. The estimated annual cost in 1983 of drug-related hospitalizations of the elderly and of their post-hospital treatment was $4.5 billion.[6] Elimination of such common drug-related problems would greatly reduce costs for both patients and the government.

In response to these and related concerns--for example, the high cost of prescription drugs--the Medicare Catastrophic Coverage Act of 1988 expanded the Medicare program to include coverage for catastrophic medical expenses and prescription drug costs that exceed $550 per year.[7] The act also requires that the Secretary of Health and Human Services establish, by no later than January 1, 1991, an electronic system for use by pharmacies that dispense drugs to Medicare beneficiaries. This system will be used primarily to (1) verify the Medicare eligibility of the drug purchaser, (2) keep drug purchase records that will show whether the deductible level has been exceeded, (3) process and pay bills, and (4) review the utilization of drugs both before and after the drug purchase.

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[5]Public Citizen Health Group, Worst Pills, Best Pills: The Older Adult's Guide to Avoiding Drug-Induced Death or Illness (New York: Pantheon, 1988).

[6]Pennsylvania Blue Shield, The Medication Passport and Drug Education Program for Senior Citizens (Pennsylvania Blue Shield, June 1985).

[7]The catastrophic drug deductible changes to $600 in 1991 and to $652 in 1992.

The basic system will consist of computers connected to participating pharmacies.[8] Information about prescription drugs and about each Medicare beneficiary's recent prescriptions will be stored in regional computers, the country having been divided into three regions. Each pharmacy that chooses to use the system will have a point-of-sale device that can communicate with the computers via telephone lines. When a request is made to fill a prescription, the pharmacist will enter information about the prescription into the point-of-sale device and receive information back from the regional computer. The stored information will be used to perform the various required functions, including paying bills and reviewing the use of drugs.

HCFA intends to enter into contracts with three drug bill processors for the implementation and operation of the system. One of these bill processors will also operate a central, coordinating organization to be known as the prime drug data center. A request for proposals has been issued by the agency and contracts are expected to be awarded by mid-January 1990.

The focus of our work has been on the proposed system for drug utilization review, a part of the overall system that HCFA is

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[8]As used in the law, the term "participating pharmacy" means an entity that is authorized under a state law to dispense covered outpatient drugs and that has entered into an agreement with the Secretary.

proposing. Two kinds of review capability are to be provided by the contractors: (1) prospective review of the drug therapy at the point-of-sale before prescriptions are filled and (2) retrospective review at some time after the drugs have been dispensed. Retrospective review includes the examination of individual prescriptions but is primarily intended to focus on the analysis of use patterns for certain sets of prescriptions (for example, examining the records for a particular physician to look for evidence of excessive prescribing of certain drugs).

The overall system called for by the Medicare Catastrophic Coverage Act has multiple purposes, and its development and implementation will be a complex undertaking. It is obvious from the RFP that HCFA has devoted a great deal of effort to the record keeping and bill processing parts of the system. However, in our previously cited report, we expressed several concerns about the system as it was characterized in a draft of the request for proposals. And although HCFA has made a number of improvements in the final version of this document, we remain concerned about three areas: (1) drug safety, (2) system development and implementation, and (3) pharmacy participation. I now want to turn to a consideration of these areas of concern.

DRUG SAFETY ISSUES

The drug utilization review part of the HCFA system is focused

on safety matters, and our concerns in this area are threefold: (1) the types of safety information that will not be available from the system, (2) limitations on the amount of information in the system, and (3) lack of a basis for assuring appropriate prescribing and dispensing practices.

HCFA has described the proposed system as "a fundamental...[drug utilization review] system...designed to be evolutionary and dynamic." However, while we understand the need for some flexibility in determining system details, we believe that several safety issues need to be resolved and that the ultimate scope of the system should be reconsidered while potential vendors are responding to the request for proposals.

Safety Information Not Available

Several types of information that can help a pharmacist make judgments about the appropriateness of prescriptions will not be available under the proposed drug utilization review system. Though the system will contain information about the drugs prescribed for the patient, the individual's medication profile will not be displayed to the pharmacist, who will therefore not know the patient's full drug regimen. Also, the system's data base will not contain information about beneficiaries' drug allergies or the use of over-the-counter drugs.

Absence of the medication profile as a feature of the HCFA system seems to put the agency's plan in conflict with the Conference Report on the Medicare Catastrophic Coverage Act of 1988, which states that all participating pharmacies will review the medication profile of all beneficiaries before filling the prescription and make a judgment about the appropriateness of the medication. HCFA's proposed drug utilization review system will provide four kinds of information: (1) an alert to the potential of a serious drug interaction for a limited number of drugs, (2) the names of any drugs that may interact, (3) the date that the potentially interacting drugs were last dispensed and (4) the prescription number from the newly submitted prescription that was the source of the problem. But, again, no other details on the patient's medication profile will be supplied. Thus, the pharmacist using the HCFA system will not know the full drug regimen that the patient is currently receiving.

The legislation encourages pharmacists to counsel patients on proper prescription drug use. However, without a medication profile and lacking full information on interacting drugs--for example, dosage of an interacting drug and the identity and location of the prescribing physician--the participating pharmacists will be constrained in their ability to counsel patients. Depriving the pharmacist of this information--which will be available in the system's data base--will, in our opinion, unnecessarily lessen drug safety and complicate the pharmacist's

task of dealing with alerts for possible drug interactions.

In another example of safety information that will not be available, the HCFA request for proposals does not call for the system data base to contain information about a patient's drug allergy or cross sensitivity problems.[9] Drug reactions arising from allergies and cross sensitivity are an easily preventable source of morbidity and mortality, especially in the elderly population.

Information from the U. S. Naval Pharmacy in San Diego demonstrates the importance of storing allergy information in a drug utilization data base.[10] In filling approximately 833,000 prescriptions in outpatient pharmacies between April 1988 and March 1989, the naval pharmacy recorded 178 alerts of a life-threatening or potentially life-threatening nature based upon the allergies as compared to 74 alerts based upon drug-to-drug interactions. Of these 178 alerts, the prescribing physician made immediate changes in 56 cases--compared to only 11 for drug-to-drug interaction cases. These physicians, like most others, are

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[9]Drug allergy is defined as the response elicited by an allergen (a substance capable of inducing a specific, acquired alteration in the capability of a human to react) after an allergic state has been established. A cross sensitivity is a sensitization to a substance induced by exposure to another substance having cross-reacting antigens.

[10]This system was described in an earlier GAO report, Prescription Drugs: Information on Selected Drug Utilization Review Systems, GAO/PEMD-89-18 (Washington, D.C.: May 1989).

generally less aware of a patient's drug allergies than they are of the potential for drug-to-drug interactions, but they are receptive to changing prescriptions because the naval pharmacy system is providing new information to them.

In another study conducted at nine community pharmacies in central Indiana during the fall of 1987, researchers from Purdue University examined 5,874 prescriptions. They identified 192 instances of prescribing errors. In 8 of these 192 cases (4.2 percent) errors were due to physicians failing to account for information about the patient's current or previous drug therapy which resulted in an alert for severe drug-to-drug interaction. In another 9 cases (4.7 percent) physicians failed to account for information about the patient's allergies/sensitivity to drugs in writing prescriptions.[11] A drug utilization review system which contained allergy information could help to rectify this kind of problem.

Another category of information not available from the proposed HCFA system is the names of over-the-counter drugs that the patient is using. Over-the-counter drugs are recognized as therapeutic agents, but they can be hazardous to the elderly, especially those with multiple and complex drug regimens.

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[11]M.T. Rupp, S.W. Schondelmeyer, G.T. Wilson, and J.E. Krause, "Documenting Prescribing Errors and Pharmacist Interventions in Community Pharmacy Practice," American Pharmacy, NS28 (1988), pp. 30-37.

An additional reason for being concerned about over-the-counter drugs is that some prescription drugs have recently been switched to over-the-counter status while other important prescription drugs are soon to be converted. For example, by 1990, cimetidine will become an over-the-counter drug, to be followed by such drugs as hydrochlorothiazide and propranolol. Cimetidine has been shown to interact frequently with many drugs of both the over-the-counter and prescription variety. In the absence of over-the-counter drug information in the proposed data base, the elderly patient is at risk of unpredicted adverse drug interactions, therapeutic duplications, and other problems.

Limitations on the Amount of Information That Will be Available

The proposed drug utilization review system will have limited ability, at least in its initial form, to detect severe drug-to-drug interactions, excessive dosages, and duplicative drug therapies.

In its draft request for proposals, HCFA identified 225 drugs to be examined for drug-to-drug interactions, 45 drugs to be examined for excessive dosages, and an initial 50 to 60 generic drug entities considered to be therapeutic duplicates. We and other reviewers of this document registered concern about the relatively small number of drugs that will be in the system data base and about some of the individual drugs included in or excluded

from HCFA's lists.

The final request for proposals says that the initial data base (the one that will begin operation in January 1991) will have (1) information on 225-250 "severe" drug-to-drug interactions, (2) maximum daily dosage levels for 40-50 drugs, and (3) information on 50-60 generic drugs considered to be therapeutic duplicates. The request for proposals provides no lists but says they will be developed and provided to the drug bill processors before implementation. This move by HCFA may provide an opportunity for stakeholders and medical experts outside of the agency to provide input to the final lists. Also, the request for proposals now notes the possible need to increase the number of drugs for which information is stored on drug-to-drug interactions, maximum daily dosages, and therapeutic duplicates. We think this is a step in the right direction and believe that it would be useful to begin consideration of the need to expand the coverage of the data base even before the contracts are signed in January. We are still concerned that the initial system may afford only minimal protection.

We also think that, in formulating the lists a better system might be designed if HCFA were to establish a board of experts to deliberate some of the issues and provide advice to the agency. This more visible, systematic approach would also allow the Congress to more readily observe the process and be assured that an

appropriate balance is achieved between system complexity and cost on the one hand and drug safety on the other.

We have one other concern about HCFA's drug lists--a concern that HCFA should be able to address before producing their final versions. We believe that the lists should consider the geriatric population specifically, rather than focusing on drugs that may be dangerous to the general population. In HCFA's draft request for proposals, only 7 of the top 25 drugs prescribed to the elderly were included in the HCFA listing of 250 drugs that were to be checked for interactions. Reliance on information from the general population may cause drugs that have severe consequences for the elderly to be overlooked.

Similarly, adverse drug reactions due to excessive dosage may be experienced more frequently in a geriatric population, yet clinical trials where dosage is tested do not generally involve geriatric patients. Again, only 7 of the top 25 drugs prescribed for the elderly were on HCFA's list in the draft request for proposals. The final request for proposals recognizes that "Medicare beneficiaries, whose elimination of many drugs may be less efficient (e.g., drugs excreted by the kidneys, etc.), are particularly susceptible to adverse effects of drugs even at the recommended adult daily dosages." However, the proposed drug data base will include only 40-50 drugs to be examined for maximum daily dose based upon the labeling of the drug and the age of the

beneficiary. Unless HCFA expands its list of drugs other drugs important to the elderly will not be screened at all and many potential drug reactions will not be identified.

Information specific to the elderly should also be considered for therapeutic duplicates but is not included in the request for proposals. A comprehensive drug utilization review system would include a therapeutic classification index for more than the 50 to 60 drugs accounted for in the system and would be capable of alerting the pharmacist of these duplicates.

Lack of Basis for Assuring Appropriate Prescribing and Dispensing Practices

The legislation says that the drug utilization review system should identify (1) instances or patterns of unnecessary or inappropriate prescribing practices for covered outpatient drugs, (2) instances or patterns of substandard care with respect to such drugs, and (3) potential adverse reactions. To create the basis for such activities, the Secretary of Health and Human Services is to establish standards for prescribing drugs based upon accepted medical practice.

The primary means of carrying out that part of the mandate that pertains to finding patterns of unnecessary or inappropriate care is the retrospective review, which is to be conducted on all

claims--both electronic ones submitted by the pharmacies via the point-of-sale devices and paper claims submitted by beneficiaries. There are many potential problems to be addressed by a retrospective review, including the prescribing of an unlikely combination of drugs for an individual, unnecessary prescriptions, and prescriptions which lead to substandard care. Some such problems may indicate fraud, abuse, or misuse, while others may simply be due to lack of access on the part of the physicians and pharmacists to a complete medication profile.

We have two concerns about HCFA's proposed procedures for carrying out retrospective drug utilization review. First, they appear to be focused on the types of analyses that might reveal fraud, abuse, or misuse but do not appear to be oriented toward the quality-of-care issue. For example, there is no discussion in the request for proposals of merging patient diagnosis information from the Medicare Part B claims data with prescription information, as mentioned in the Conference Report on the Medicare Catastrophic Coverage Act of 1988.[12] This omission may indicate that a review of the appropriateness of a drug therapy will not be included in HCFA's system. In any case, without information on both the prescription and the patient's diagnosis, it is not clear how the

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[12]U.S. Congress, House of Representatives, Medicare Catastrophic Coverage Act of 1988: Conference Report, Report No. 100-661, 100th Cong., 2nd sess. (Washington, D.C.: U.S. Government Printing Office, 1988).

appropriateness of the medication provided will or can be determined.

A second, related issue pertains to the establishment of standards that the legislation presumes would be used to search for patterns of inappropriate prescribing and dispensing practices. The law states that "...the Secretary shall incorporate standards from such current authoritative compendia as the Secretary may select; except that the Secretary may modify such a standard by regulation on the basis of scientific and medical information that such standard is not consistent with the safe and effective use of the drug." The request for proposals is silent on how the standards should be used to identify patterns of inappropriate practice.

The absence of discussion about standards suggests again that little attention will be given to problems associated with poor quality of care. We believe that attention needs to be given to the application of appropriate standards and that the Secretary may wish to seek advice from professional organizations such as the American Medical Association, the American Pharmaceutical Association, and the Pharmaceutical Manufacturing Association.

In order to help ensure that appropriate reviews are performed and that the results of these studies are interpreted and used properly, we believe that consideration should be given to having

a drug utilization review board oversee the development of standards for alerts, design of retrospective studies, and the analysis of their results. The board could be composed of practicing physicians with geriatric-clinical backgrounds, clinical pharmacologists, pharmacists, pharmaco-epidemiologists, and other individuals with recognized expertise in drug prescribing, drug dispensing, drug utilization review, and medical quality assurance.

SYSTEM DEVELOPMENT AND IMPLEMENTATION

The drug bill processors, under HCFA's direction, must develop and implement their parts of the system, including those for drug utilization review, by January 1991. For any new system to demonstrate a capability to perform its intended mission, it must be tested comprehensively and realistically. It must be shown, for example, that prospective drug utilization reviews will be able to swiftly detect potentially adverse drug reactions without a high percentage of false-positive alerts, which would frustrate patients, pharmacists, and physicians. In addition, it must be shown that information can be efficiently exchanged between the three independently developed regional systems of the three drug bill processors. Since each contractor will be developing its own system, HCFA, in effect, is testing not one but three systems and the communication among them.

Before the system becomes operational, it should be tested under conditions that closely approximate those anticipated in the real world in terms of, for example, the anticipated number and type of transactions at peak times, likely error rates for data entry, the need for purging the system of old data, and probable communication and computer problems. We have concerns about whether the planned testing is sufficiently realistic and whether there is enough time to perform the tests and then correct any problems that are found.

Few details about system testing are described in the request for proposals. HCFA's intended test of the system by means of dummy prescriptions would not, as we understand their plan, constitute a trial of the system under realistic conditions.

The overall time of one year for the contractors to develop, test, and implement software seems unrealistically short. Similar experiences in other government agencies have demonstrated that development of this type of system takes at least six months to one year from specification development--for example, deciding what information to include and how it will be used--to final product development. Beyond this, system testing and software refinement take additional time. Usually, the software requires several revisions to become a satisfactory product. HCFA has no contingency plans for dealing with problems that the testing they intend to perform may uncover. There appears to be no room in

HCFA's schedule to correct problems found during the testing phase, unless such problems turn out to be very small and inconsequential ones.

HCFA has long and valuable experience of operating the Medicare and Medicaid programs, but the drug benefit program is a new challenge because of the national electronic system called for by the legislation. And, although HCFA officials have expressed confidence that they will be able to establish a system on time, we have concerns about how completely and realistically that system will be tested.

PHARMACY PARTICIPATION ISSUES

The success of HCFA's program rests, to some extent, on its success in getting a majority of pharmacies to participate in the program. The value of prospective drug utilization reviews by means of a centralized system is lost at nonparticipating pharmacies, since all of their transactions will be handled as paper claims submitted to the drug bill processors by the beneficiary. No prospective drug utilization review will occur in those instances, and thus the health and safety benefits of such a review will not be available to beneficiaries who patronize a nonparticipating pharmacy. While HCFA expects an 80 to 90 percent pharmacy participation rate in the first year, the basis for that estimate is not clear.

While the obtaining of business from Medicare patients and the use of drug utilization review for improving the quality of care a pharmacy can offer to patients should argue strongly for pharmacy participation, there are also many reasons why a pharmacy may hesitate to participate. For example, there may be concerns about the display capacity of point-of-sale devices and the operating costs, including telecommunication charges. Other concerns might include uncertainties about the response time, software and hardware requirements for existing or future pharmacy computer systems, the types and form of data to be collected by the system, the system's potential to usurp the pharmacist's professional judgment, increased liability, and the frequency of updates on drug prices.[13] Some pharmacists are concerned by the fact that their existing drug utilization review system contains as much or more information than the system being proposed by HCFA. They question the wisdom of a change to a system that offers less quality of care than the one they already have.

At this time, the material incentives for participation that HCFA offers to the pharmacies are either a point-of-sale device for pharmacies that are not currently computerized, or its cost equivalent in software modifications for those that must modify their computer systems, plus a dispensing fee for prescriptions

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[13]The Medicare Catastrophic Coverage Act of 1988 mandates semiannual pricing updates. Currently prices are updated weekly or biweekly. The industry believes that semiannual updates are not economical for them in that prices rise more often than semiannually.

that are paid for by Medicare. Participating pharmacies will receive $4.50 for each prescription filled for patients who meet or exceed their deductible level. Nonparticipating pharmacies will receive a $2.50 dispensing fee for eligible beneficiaries. To deal with one cost concerns of pharmacies, HCFA has prepared a technical amendment to the Medicare Catastrophic Coverage Act of 1988 to authorize reimbursement for the cost of software changes to existing in-store pharmacy systems so that such systems can be used to submit Medicare drug bills electronically without using the special point-of-sale device.

We believe, as does HCFA, that the pharmacy participation rate is critical to the success of the electronic drug utilization review. A high rate of participation in a good system can have a direct, positive effect on the quality of care for Medicare beneficiaries. Our view, therefore, is that HCFA should not simply delegate the responsibility for gaining a high rate of pharmacy participation to the drug bill processors but rather should remain actively involved. Contingency plans to improve participation rates, including possible incentives, should be considered now so that they can be implemented quickly if needed.

SUMMARY

In summary, we believe that HCFA's drug utilization review system, at least in its initial form, will fall short of

accomplishing the legislative mandate in a number of areas.

HCFA will not provide a complete profile of the patient's medication to the pharmacist. And, at least initially, the system will identify drug-to-drug interactions for only 225-250 drugs, will detect prescribed dosages that exceed the maximum daily dosage for only 40-50 drugs, and will limit drug duplication checks to 50 to 60 drug entities considered to be therapeutic duplicates. The system will not include some critical clinical information pertaining to Medicare beneficiaries, such as drug allergies and use of over-the-counter drugs. The exclusion of this information can have significant adverse effects on the quality of care experienced by Medicare beneficiaries.

While the draft request for proposals contained lists of drugs that the electronic system would check for drug-to-drug interactions, excessive daily dosage, and duplicate drug therapy, HCFA now plans to revise the lists based on reference sources and expert opinion. However, we remain concerned about the lack of visible and systematic procedures for generating such lists specifically for the elderly population.

The focus of HCFA's retrospective drug utilization review appears to be on fraud and abuse or misuse. There is no indication in the request for proposals of plans to link a patient's diagnostic information from Medicare Part B claims data to

prescription drug data in order to assess the appropriateness of drug therapy. We also found no clearly defined strategy or organizational structure for developing standards for appropriate prescribing and dispensing practices, and such standards are needed to carry out the legislative intent.

In addition, we remain concerned about HCFA's plan to develop and implement the system. We believe that test plans are not sufficiently developed and that the actual tests may not be comprehensive and realistic. We further believe that the planned testing period will be too short to identify and correct the sorts of problems that typically occur with a new and complex technology.

To ensure a high participation rate among pharmacies, we believe that HCFA may have to become more active in gaining the confidence of pharmacies and that contingency plans for increasing pharmacy participation should be developed now so that they can be quickly implemented if the initial participation rate is low.