112632

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Problems Remain In Reviews Of Medicaid-Financed Drug Therapy In Nursing Homes

The Department of Health and Human Services requires that medications financed by Medicaid for nursing home patients be reviewed monthly by a pharmacist or registered nurse. Monitoring of drug therapy for elderly people is particularly important because often they have more than one ailment and may take several drugs.

GAO found that the Department has not adequately dealt with two major problems encountered by reviewers.

--There is no readily accessible, single source of information on the monitoring and use of drugs.

--The Department has not defined the scope of a "medication review."

The Secretary of Health and Human Services should direct the Administrator, Health Care Financing Administration, to take action to resolve these problems.

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses problems facing pharmacists and registered nurses who are responsible for performing monthly reviews of the drugs taken by Medicaid nursing home patients. The Department of Health and Human Services needs to take regulatory action and to disseminate in a systematic manner existing information about drug use by geriatric patients.

We are sending copies of this report to the Director, Office of Management and Budget, and the Secretary of Health and Human Services.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

PROBLEMS REMAIN IN REVIEWS OF MEDICAID-FINANCED DRUG THERAPY IN NURSING HOMES

D I G E S T

Medicaid pays for about half of all nursing home care in the United States. To help ensure the quality of that care, the Department of Health, Education, and Welfare (HEW) 1/ has set up a number of procedures, including a monthly review of each patient's drugs to determine if they are still needed, effective, and safe for the patient.

GAO found that medication reviews could be more effective if reviewers--pharmacists or registered nurses--had ready access to

--a single source of authoritative information on drugs commonly used in treating elderly patients and

--a clear definition of the scope of those reviews.

Elderly persons are particularly vulnerable to adverse reactions to drugs because of the infirmities of old age and because many take more than one drug.

NEED FOR ADEQUATE DRUG CRITERIA

The most widely used source of drug information is the Food and Drug Administration-approved labeling for each prescription drug. HEW has known for at least a decade that neither labeling nor any other single

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1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

source of drug information meets the needs of all health professionals. (See p. 7.)

Labeling for some drugs often used in the treatment of nursing home patients either does not

--contain specific information on how the drug should be monitored or

--describe the implications of using multiple drugs which affect the same system within the body.

Medication reviewers must rely on their personal drug knowledge or search for other sources of information, which may not be reliable. (See p. 9.)

GAO reviewed the records of randomly selected Medicaid nursing home patients to determine whether drugs were monitored and used in accordance with criteria based on standards developed by five Professional Standards Review Organizations (PSROs)--groups of local physicians whose duties include determining whether health care provided under the Social Security Act is of high quality--and a school of pharmacy with the advice and assistance of practicing physicians and other health professionals. This review disclosed that about 81 percent of the estimated 48,600 Medicaid patients residing in nursing homes in five States who were receiving 10 selected drugs were not being tested as frequently as recommended. (See p. 20.)

Using the limited criteria available, GAO identified a few cases where patients took combinations of tranquilizers and sedatives that a PSRO characterized as "inappropriate utilization." (See p. 25.)

Another small group of patients were taking drugs that the labeling clearly stated should not be used for one or more of their medical conditions. (See p. 28.)

During 1979 HEW issued new regulations designed to improve labeling information. It considers this an important step in the development of a drug compendium. Legislation was also introduced in the Congress which provides for developing a Federal Drug Compendium or Index. Both improved labeling and a single source drug guide should alleviate the drug information problem; however, these projects will take several years to complete. GAO believes that HEW is responsible for disseminating on a timely basis information on the monitoring and usage of the relatively few drugs given to nursing home patients by using the knowledge and expertise of PSROs and others. (See p. 29.)

HEW HAS NOT PROVIDED ADEQUATE MEDICATION REVIEW GUIDELINES TO PHARMACISTS AND NURSES

In 1974 HEW began requiring that the medications given Medicaid nursing home patients be reviewed monthly by a pharmacist or registered nurse. However, it has never clearly defined what it means by medication review. As a result, pharmacists and nurses have developed their own interpretations. (See p. 37.)

Reports issued by study groups since medication review became a requirement indicated a need for training in making a medication review. (See p. 38.) Some training courses and materials were developed at HEW's expense, but HEW does not know how many pharmacists and registered nurses received this training or the extent of unmet training needs. (See p. 41.)

Some pharmacists were unsure of their qualifications to review medications; others either were not sure of what a medication review should consist of or were inhibited in making drug therapy recommendations because of possible resentment by attending physicians. At some of the homes GAO

visited, pharmacists performed less comprehensive reviews than suggested in HEW-funded training materials. Some registered nurses did not consider all aspects of patient medications; however, pharmacists or physicians at those homes were also reviewing medications. (See p. 43.)

POTENTIAL CONFLICTS OF INTEREST

Pharmacists making medication reviews at many of the homes GAO visited were associated with the retail pharmacies which filled prescriptions for the patients, creating a potential conflict of interest. Although GAO found no evidence that pharmacists were not objective in their reviews, it believes the two functions should be separated whenever possible to preclude conflicting interests. (See p. 50.)

RECOMMENDATIONS TO THE SECRETARY OF HEW

The Secretary of HEW should direct the Administrator, Health Care Financing Administration (HCFA), to:

--Gather the monitoring and usage criteria that have been developed by PSROs and others for drugs commonly taken by nursing home patients and (1) send the criteria that HCFA judges to have merit to every nursing home participating in the Medicare and/or Medicaid programs, (2) revise and expand the criteria as PSROs and others gain experience in medication reviews and send these revisions to nursing homes, and (3) share the criteria with the Food and Drug Administration for use in its efforts to improve prescription drug labeling.

--Direct the National Professional Standards Review Council to promote continued development of additional drug-monitoring criteria for drugs commonly used in nursing homes, with particular emphasis on drugs and combinations of drugs for which few or no criteria are currently available.

--Incorporate in nursing home regulations a clear definition of the scope of a medication review for both pharmacists and registered nurses.

--Issue regulations requiring separation of pharmacist medication review and drug vendor functions whenever feasible.

HEW, APhA, AND PSRO COMMENTS

HEW, the American Pharmaceutical Association (APhA), and the Colorado PSRO commented on a draft of this report. HEW, APhA, and the Colorado PSRO all generally agreed with the first two recommendations with the stipulations that the criteria be clearly identified as screening criteria, that the criteria are subject to modification to meet local conditions, and that deviations from the criteria are acceptable where medically indicated.

The Colorado PSRO believes GAO's last two recommendations are sound. APhA and HEW disagreed with the recommendation that the scope of a medication review be incorporated in nursing home regulations. They said GAO was suggesting that medication review methodology be incorporated in the regulations. The wording of that recommendation has been clarified.

HEW and APhA did not agree with the recommendation that drug vending and medication review be separated whenever feasible. HEW believes that regulatory action is needed "only if there is evidence of actual harm to patients" and because fees pharmacists get for dispensing drugs subsidize medication reviews by the pharmacists. APhA disagreed on the basis that adequate reimbursement for these services was a more appropriate way to prevent potential conflicts of interest from becoming a reality. GAO continues to believe that drug vending and medication reviews should be separated whenever feasible to remove financial disincentives for medication reviewers who also sell drugs to recommend the discontinuance of unnecessary drugs.

Tear Sheet

Contents

ABBREVIATIONS

APhA	American Pharmaceutical Association
CNS	central nervous system
FDA	Food and Drug Administration
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HEW	Department of Health, Education, and Welfare
ICF	intermediate care facility
PSRO	Professional Standards Review Organization
SNF	skilled nursing facility

CHAPTER 1

INTRODUCTION

No drug is absolutely safe, and not every drug is always effective for an individual patient or equally effective in all patients. The population subject to the hazards of drugs is sizable, and their drug usage is extensive. Drugs pose particular hazards for elderly persons because of the infirmities associated with old age and their greater vulnerability to adverse drug reactions. Such adverse reactions are even more likely in the many elderly patients who take multiple medications.

The United States is becoming more and more a Nation of elderly persons. The number of elderly persons is increasing in both numbers and as a percentage of the total population. In 1900, the 3 million elderly (those 65 and over) were 4 percent of the population. In 1940, the 9 million elderly were 7 percent of the population. In 1977, the 23 million elderly were 11 percent of the population. The Census Bureau estimates that in 1990 there will be 29 million elderly constituting 12 percent of the population.

The chances that elderly persons will be cared for in a nursing home increase as they grow older. About 1.1 million elderly persons were in nursing homes in 1977, and about 40 percent of them were 85 and over. Looking at the total elderly population in 1977, about 5 percent were in nursing homes. About 10 percent of those 75 and over and more than 20 percent of those 85 and over were in nursing homes. Noninstitutional alternatives to nursing home care are becoming more available, but for the foreseeable future, large numbers of the elderly will continue to be cared for in nursing homes. Drug therapy is a principal element of care for many elderly nursing home patients.

As a group, the elderly take more drugs than younger persons, and elderly nursing home patients take more drugs than the noninstitutionalized elderly. A sizable proportion of drugs prescribed for the elderly are long-term maintenance drugs, used primarily for controlling chronic diseases. A

1976 Department of Health, Education, and Welfare (HEW) 1/ report shows that 54 percent of nursing home patients were receiving 6 or more drugs at a time, with some receiving as many as 23 drugs. The study was based on a random sample of nursing homes throughout the United States.

Within HEW, the Food and Drug Administration (FDA) is responsible for ensuring that prescription drugs available to the entire U.S. population are safe and effective. Another HEW component, the Health Care Financing Administration (HCFA), as a contributor to the cost of care for Medicaid nursing home patients, has set up procedures to promote the quality of that care. One way HCFA attempts to ensure the quality of drug therapy is through a process called medication review.

WHY MEDICATION REVIEW IS IMPORTANT

Medication review involves determining whether the patient needs the drug and whether it is properly administered, effective, and safe. All drugs have at least some potential to cause adverse reactions; this is an inevitable by-product of the pharmacological characteristics that make them useful.

HEW regulations, applicable to nursing homes receiving Medicaid funds for the care of patients, require monthly review of patient medications. For older persons, medication review is especially important because:

--Patients over age 65 experience more adverse drug reactions than younger persons because their cardiovascular and nervous systems are more sensitive to some drug actions and because drugs often accumulate in the body when there is poor liver circulation or when the kidneys function inefficiently. (Most drugs used today are metabolized in the liver and eliminated through the kidneys.)

1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

--As a group, long-term care patients (usually the elderly) take several drugs, which makes them more susceptible to adverse drug reactions and interactions or lack of therapeutic response.

--Elderly patients normally have more than one chronic medical condition, which adds to the risk of taking drugs because a drug used to treat one condition may be contraindicated due to the presence of other conditions.

MEDICAID-FINANCED CARE OF THE ELDERLY

The 1965 amendments to the Social Security Act (Public Law 89-97) established the Medicaid program (title XIX), effective January 1, 1966. Medicaid is a grant-in-aid program under which the Federal Government pays 50 to 78 percent of the cost of providing medical assistance to individuals whose income and resources are not sufficient to pay for health care, with the States and local governments paying the remaining 50 to 22 percent. On the Federal level, Medicaid is administered by HCFA. Medicaid-financed care includes nursing home care and prescription drugs.

Nursing home care

Nursing home care is provided in skilled nursing facilities (SNFs) and intermediate care facilities (ICFs). SNF services are provided to those individuals who need, on a daily basis, skilled nursing care or other skilled rehabilitation services which, as a practical matter, can only be provided in a SNF on an inpatient basis. The individuals needing SNF care do not require the constant availability of the full range of medical services of an acute-care hospital but need services ordered by a physician which must be provided by, or under the direct supervision of, trained nursing personnel. ICF services are health-related care and services provided to individuals who do not require the degree of treatment provided in hospitals or SNFs. However, because of their mental or physical conditions, these individuals require care (above that of room and board) which can only be provided in an institution.

Nursing homes participating in Medicaid receive two types of State inspections and evaluations at least annually. The State Medicaid agency or its designee evaluates the care being provided to each Medicaid patient. In addition, the State licensing agency determines whether the facility is in

compliance with Federal and State regulations for the types of care (e.g., skilled, intermediate) provided and certifies facilities found to be in compliance.

In 1977, about 13,500 nursing homes in the United States were certified to provide SNF and/or ICF services under the Medicaid program: 2,900 homes provided SNF care only, 4,400 homes provided both SNF and ICF care, and 6,200 homes provided ICF care only. Medicaid payments for ICF services were authorized by the December 1971 amendments to the Social Security Act (Public Law 92-223), while SNF services have been authorized since the inception of the Medicaid program. In fiscal year 1977, Medicaid payments to nursing homes (including both State and Federal shares) were about $6.4 billion. Medicaid currently pays for about half of all nursing home care purchased in the United States.

Prescription drugs

In fiscal year 1977, Medicaid paid just over $1 billion for prescription drugs. Forty-four percent of that billion dollars bought prescription drugs for the elderly, even though only 17 percent of all Medicaid recipients are elderly.

PURPOSE AND SCOPE OF REVIEW

Because of the major role drugs play in the treatment of elderly patients in nursing homes and the potential hazards of drug therapy, we evaluated the effectiveness of the medication review portion of HEW's regulations and procedures. Although these regulations apply to both the Medicaid and Medicare programs, we limited our review to Medicaid nursing home patients because the treatment period of Medicare nursing home patients is generally of limited duration--a median stay of 24 days.

Our review included work at HEW headquarters in Washington, D.C.; HEW regional offices in Atlanta, Boston, Dallas, Kansas City, and San Francisco; State agency offices in California, Georgia, Iowa, Kansas, Massachusetts, and Texas; and 68 nursing homes in these six States. These States were selected because they are geographically dispersed and because about 30 percent of all nursing homes are located in them.

The nursing homes we visited in each State were randomly selected. (See app. I.) At each home we interviewed facility officials, facility consultants, and attending physicians

when they were available; identified medication review procedures and practices; and reviewed medical records of randomly selected Medicaid patients in two samples. The first sample was restricted to patients who received one or more of certain selected drugs to determine if these patients received laboratory tests or other tests they needed. The second random sample covered all Medicaid patients in the nursing homes. Information relating to the management and review of the entire drug regimen was extracted from each patient's medical records and analyzed by our Chief Medical Advisor, a physician. Data were obtained on patients for the period January 1976 through October 1977 in Kansas and July 1976 through August 1978 in the other five States.

The table below shows the number of nursing homes visited and the number of patient records reviewed:

	Nursing homes				Patient records reviewed		
State	In sample	SNF only	Combined SNF & ICF	ICF only	In sample I	In sample II	Total (note a)
Georgia	4	1	3	-	42	32	66
Iowa	6	-	-	6	64	43	92
Kansas	24	-	2	22	167	(b)	167
Massachusetts	9	1	2	6	83	63	131
Texas	11	1	2	8	119	74	177
	54	3	9	42	475	212	633
California	14	14	-	-	125	95	188
Total	68	17	9	42	600	307	821

a/There were 86 patients included in both samples.

b/Kansas was not included because sample II was not designed until after we finished our visits there.

California is shown separately from the other five States because we discontinued our fieldwork after visiting 14 of a planned 20 homes when it became apparent that the results there would not be substantially different from those in the other States where our fieldwork had been completed. For statistical reasons discussed in appendix I, we cannot project our California patient data along with those for the other States. Our projections for the other States are based on the combined or "clustered" patient data for those States (five in sample I and four in sample II).

At the Federal and State levels, we interviewed officials, analyzed nursing home regulations, identified procedures for inspection and review of nursing homes, and examined reports by State reviewers inspecting the selected nursing homes. We also compared State Medicaid agency vendor payment records with patient records in the nursing homes to identify instances where tests had been performed and paid for but not recorded in the patient records kept in the nursing homes. We researched professional medical and pharmaceutical journals and obtained assistance on drug-technical matters from FDA and on drug-monitoring procedures from selected Professional Standards Review Organizations (PSROs), physicians, and registered pharmacists.

We also spoke with representatives of the American Pharmaceutical Association (APhA).

CHAPTER 2

HEW NEEDS TO ASSURE THAT MORE SPECIFIC INFORMATION ON THE MONITORING AND USE OF DRUGS IS AVAILABLE TO HEALTH PROFESSIONALS

The most widely used and readily accessible source of information on drugs is drug labeling, which is developed by the drug manufacturer and approved by FDA. HEW has known for at least a decade that drug labeling by itself is not adequate to meet the needs of health professionals. Over the past decade several studies--some funded by HEW--have reported that a single source of accurate, complete information on drugs should be developed and widely distributed to health professionals. This information source, or drug compendium, does not yet exist, and we believe that its absence has hampered pharmacists and registered nurses in making medication reviews.

Much of the information that would be in a drug compendium already exists in drug labeling, but sometimes this information is not sufficiently specific. For example, labeling did not specify the frequency with which tests should be performed on patients to monitor the effects of certain drugs or the precautions to be followed when several drugs are used concurrently. With the financial support of HEW, information of this type has been developed--and placed on file at HEW headquarters--by five PSROs 1/ and a school of pharmacy on several drugs or classes of drugs taken by substantial numbers of nursing home patients. Using information from these sources as criteria, we analyzed 10 drugs taken by a random sample of patients at 68 nursing homes in six States and found that many patients were not receiving the recommended tests to monitor whether the drugs were having the desired effect or whether an undesirable effect had resulted. In a second random sample, we found that, of the large number of patients who daily received one or more drugs which depress the central nervous system, a few received combinations of tranquilizers and sedatives which one PSRO characterized as "inappropriate utilization." In our second

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1/PSROs are groups of local physicians whose responsibilities include determining whether health care provided under the Social Security Act meets professionally recognized medical standards.

sample we also found instances where patients took drugs which, according to the drug labeling, were contraindicated for their medical condition.

We believe that an underlying cause of the questionable drug monitoring and usage practices we noted was HEW's failure to provide the readily accessible source of complete and accurate drug information it has recognized is needed. In June 1979, FDA issued final regulations directed at improving drug labeling information, which FDA believes to be an important step in developing a drug compendium. In addition, legislation was introduced in the Congress in 1979 which includes provisions for developing a single source drug reference.

Because of the significant role drugs play in the treatment of nursing home patients and because of the greater susceptibility of the elderly to drugs, we do not believe HEW should wait for results of the drug labeling improvement program or development of a compendium. PSROs and others have already developed guidelines on the monitoring and use of some drugs, or classes of drugs, taken by many nursing home patients, and this information could be used now by nursing home pharmacists and registered nurses in monitoring patient drug therapy. We, therefore, believe that HEW should evaluate the drug criteria already available and disseminate those it considers to have merit to nursing homes as soon as possible as an interim measure pending publication of a drug compendium. Furthermore, these criteria should be of immediate value to FDA in its drug labeling improvement program and in developing a drug compendium.

LACK OF SPECIFIC DRUG INFORMATION HAMPERS HEALTH PROFESSIONALS IN MANAGING PATIENT MEDICATIONS

Drug information is needed by a variety of health professionals, including physicians, pharmacists, and registered nurses. While physicians are the only professionals in the above group who can prescribe drugs and thus have primary responsibility for monitoring their nursing home patients, pharmacists and nurses also have monitoring roles. For example, pharmacists may check prescriptions for new drugs to determine compatibility with other drugs the patient is taking, and nurses observe patients daily for evidence that the drugs taken are having the desired therapeutic effect and for signs of undesired side effects. As discussed in chapter 3, HEW also requires monthly reviews of nursing

home patient medications by pharmacists and registered nurses. These reviews are intended to assist the physician in monitoring the patient's drug regimen.

For at least 10 years, studies have reported that health professionals were in need of better information on prescription drugs, that HEW should assume a greater role in providing this information, and that a solution would be developing a drug compendium. These studies concluded that important drug information was not always readily accessible or that the information which was available--including drug labeling--was not always complete and objective. We found that drug labeling on at least some drugs does not contain sufficient specific information on how the drugs should be monitored or be used in conjunction with other drugs.

Studies have reported a need for better drug information

In 1969, an HEW-established Task Force on Prescription Drugs issued a final report which discussed the problems health professionals--particularly physicians--had obtaining access to complete and objective information on prescription drugs. The report contained a series of recommendations, including the following:

--HEW should establish or support a publication providing objective, up-to-date information and guidelines on drug therapy based on the expert advice of the medical community.

--The Secretary of HEW should be authorized to publish and distribute to all physicians, pharmacies, hospitals, and other appropriate individuals and institutions a drug compendium listing all lawfully available prescription drugs, including such information as available on dosage forms, clinical effects, indications and contraindications for use, and methods of administration in readily accessible and comprehensive form.

The American Association of Colleges of Pharmacy, in a 1975 report discussing drug-related health services and the role of the pharmacist, cited two primary problems regarding drug information:

--There is no organized system to acquire knowledge, and the information available has been developed haphazardly.

--There is no mechanism for determining the accuracy and validity of some of the information available.

The report cites some sources of drug information used by prescribing physicians and pharmacists, which includes articles in the professional journals, drug advertisements in those same journals, several pharmacopias, hospital formularies, drug labeling (i.e., physicians' "package insert"), the Physicians' Desk Reference (which contains substantially the same information as drug labeling for about half the drug products on the market), representatives of the pharmaceutical manufacturers, and consultation with colleagues. The report points out that (1) some of the above sources may not be readily available to all physicians or pharmacists, (2) some sources do not include all marketed drugs or the latest clinical information about a drug, and (3) the completeness and accuracy of the information from some of these sources is unknown.

The report recommended that an agency, association, bureau, or foundation devote major attention to the problem and find out who needs to know, what they need to know, and how these needs can best be met with speed and economy.

The Review Panel on New Drug Regulation, established by HEW in 1975 to study FDA's policies and procedures relating to approval and disapproval of new drugs, issued a final report in 1977 which stated that there is a lack of readily available current information about drug uses and toxicities. The report said drug labeling was inadequate in that

--labeling information typically did not represent a highly critical description of the proper use of a drug and

--FDA lacked a basis for judging whether the approved labeling was still correct because there was no comprehensive system for gathering and using data on a drug's performance and effect after marketing approval.

The report stated that FDA should be the most reliable source of information about drugs available to the practicing physician and recommended that FDA develop, and revise

annually or biannually, a drug compendium which provides up-to-date information on the pharmacology of new and established drugs, including therapeutic applications, specific toxicities, and assessments of benefit and risk.

Need for a nursing home drug compendium

While the reports mentioned above dealt with drug information problems in general, a 1976 HEW report 1/ identified specific drug information problems affecting nursing home care. The report, which was based on a 1974 HEW study of long-term care problems at 288 randomly selected SNFs nationwide, stated:

> "The level and array of drugs prescribed in skilled nursing facilities suggests the need for some kind of formulary, other compendium, or drug product information file. A nursing home formulary would provide a guideline for prescribing, facilitate drug therapy management, and drug regimen review by nursing home staff, and perhaps help reduce costs. Further, a formulary, compendium, or drug information file would provide information for nursing staff in administering drugs and assessing the effects of therapy."

Drug labeling does not always contain specific information on monitoring and use

Drug labeling is intended to give physicians a clear, concise statement of the data and information necessary for safe and effective use of drugs. FDA reviews and approves the content of the labeling, which is prepared by the drug manufacturer. FDA regulations require that the labeling include information on ailments for which the drug is effective, circumstances under which it is not advisable to use the drug, warnings, precautions, possible adverse reactions, and dosage recommendations.

A 1974 poll of physicians disclosed that, while they obtained their drug information from various sources, the

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1/"Physicians' Drug Prescribing Patterns in Skilled Nursing Facilities," June 1976.

most widely used source--by 97 percent of physicians--was the Physicians' Desk Reference, a collection of substantially the same information as drug labeling for many marketed drugs. Drug labeling and the Physicians' Desk Reference were also the sources of drug information most frequently cited by the pharmacists and registered nurses we interviewed at the nursing homes visited.

We attempted to use drug labeling as criteria for determining whether a sample of patients taking certain drugs received tests with sufficient frequency to monitor each drug's effects and, on a second sample of patients, whether patients were taking too many drugs having the same therapeutic purpose. (See app. I for sampling methodology.) We found that drug labeling was vague and inadequate and that labeling did not appear to be the most appropriate vehicle for providing guidelines on some aspects of the management of multiple drugs with comparable effects.

Specifically, drug labeling is deficient in the following areas:

--Labeling for certain drugs does not contain sufficient specific information on the frequency with which tests should be performed on patients to monitor the drugs' effects.

--Labeling does not contain specific guidelines on usage limits when several drugs affecting the same body system are administered to a patient.

Testing guidelines are inadequate

For some drugs, labeling recommends that tests be performed periodically to monitor the drug effects--both whether the drug is having the desired effect and whether any undesired effect has occurred. The recommended tests include laboratory tests, such as blood counts, and other tests, such as electrocardiograms.

We identified 23 drugs frequently taken by nursing home patients for which each drug's labeling indicated that periodic tests should be made to monitor the drug's effects. Although the labeling generally stated which tests were to be performed, the recommended frequency was nonspecific, using words such as "frequently" or "periodically." 1/

1/A detailed explanation of the problems we experienced in obtaining specific monitoring guidelines for the 23 drugs is in appendix II.

FDA told us that, with regard to testing frequency, words in the labeling, such as "frequently" and "periodically," have no specific meaning. Although FDA officials expressed an opinion as to tests which were considered desirable to monitor the drugs, they stated that they were unable to recommend specific time intervals for performing the tests because there were no firm data to support monitoring at set intervals. According to these officials, the frequency of monitoring is properly left to the physician in these instances. These officials also suggested that we probably could obtain testing frequency recommendations from practicing physicians who specialized in treating nursing home patients.

We requested assistance from the American Medical Association in developing test frequencies on the selected drugs. The Association replied that technology and the state of the art have not advanced to the point where standards of this kind are entirely feasible. The Association also stated that written guidelines regarding laboratory tests and frequency of performance foster the concept of "cookbook" medicine and do not allow the individualization of care that is the essence of good medical practice.

Limits on use of comparable multiple drugs are not clear

We also reviewed the medications taken by a sample of patients to determine whether any patients concurrently received several drugs having the same therapeutic effect. We found that some patients received various combinations of drugs which depress the central nervous system (CNS). In some cases the numbers and types of drugs involved raised questions about the appropriateness of the drug combinations.

While the labeling for the CNS-depressing drugs taken by these patients generally advised caution in the concurrent use of the drug with other CNS-depressing drugs, the labeling did not provide specific guidance on the concurrent use of these drugs. As discussed beginning on page 25, one PSRO has developed some guidelines for concurrent use of tranquilizers and sedatives, both of which are CNS-depressing drugs.

SOME SPECIFIC DRUG CRITERIA HAVE BEEN DEVELOPED

Notwithstanding the American Medical Association's opinion on the practicality of written standards (see above),

we found that five PSROs and the University of Minnesota School of Pharmacy, under contract to HEW, have developed criteria for the monitoring or use of several drugs commonly taken by nursing home patients.

The criteria represent general guidelines to be used by reviewers--who are normally not physicians--to identify possible problems. In cases in which criteria are not met, the PSROs and the University generally intend that one or more physicians review the particular circumstances of the patient involved to determine whether deviations from the criteria were justified. This review assures that each patient's unique health conditions and drug responses are taken into account.

Using the specific criteria developed by these sources, we found that many patients taking these drugs did not receive tests with the recommended frequency, and a few patients received combinations of CNS-depressing drugs which the Colorado PSRO characterized as "inappropriate utilization." The criteria we used regarding contraindicated drugs came from the drug labeling and were sufficiently specific to use without additional interpretive guidelines.

PSRO criteria

PSROs are gradually assuming the responsibility for evaluating the care of skilled nursing home patients. The 1972 amendments to the Social Security Act (Public Law 92-603) authorized the Secretary of HEW to establish and support a network of nonprofit groups of local physicians called PSROs. The congressional intent of the PSRO legislation was twofold--to improve the quality of health care provided under the Social Security Act and to reduce costs for such care. As such, PSROs must determine whether health care services provided to Medicaid recipients are medically necessary, whether they meet professionally recognized medical standards, and whether the level of care provided is the most economical level possible consistent with quality care.

Each PSRO is responsible for a geographical area designated by HEW, and each State has at least one PSRO area. HEW had established 195 areas as of the end of fiscal year 1979. The PSRO organizational structure includes a National Professional Standards Review Council, which advises the Secretary of HEW and oversees the activities of State and local PSROs. A major function of the national council is criteria development and review.

As of October 1979, 51 PSROs had been funded by HEW for review of long-term care. At least five of them had developed criteria for evaluating care which included procedures for monitoring certain drugs, and one had established guidelines regarding concurrent use of tranquilizers and sedatives. Officials at the five PSROs generally stated that the drug criteria were developed because drugs are a major element of patient care or because medications were considered a problem area.

The five PSROs are those for Colorado, Utah, Western Massachusetts, Charles River Massachusetts (the suburbs west of Boston), and the Upper Peninsula of Michigan. Four of these PSROs conducted long-term care demonstration projects in which evaluative criteria, including criteria for drug therapy, were developed, field-tested, evaluated, and, in some instances, refined. The criteria development process at all five PSROs included advice and assistance from various health professionals, including practicing physicians.

Under the review systems used by the five PSROs, cases involving patients who do not meet drug screening criteria are reviewed by one or more PSRO advisory physicians to determine whether exceptions to the criteria are justified. In making this determination, the advisory physician may contact the attending physician to determine the rationale for not following the criteria. The attending physicians are notified in those instances where the PSRO believes that deviations from criteria are not justified.

The Rand Corporation, under contract to HEW, recently assessed long-term care review at 10 PSROs, including 3 used as criteria sources in our review (Colorado, Utah, and Charles River Massachusetts). Rand's August 1979 assessment report 1/ noted that some PSROs had developed explicit criteria for drug use and made the following comment regarding development and application of quality of care criteria in the area of drug use.

> "Only a few demonstrations had developed and applied quality of care criteria in the area of drug use. We consider this area to be not only important (because of its life-threatening and

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1/"The PRSO and the Nursing Home: Vol. I, An Assessment of PSRO Long Term Care Review," the Rand Corporation, August 1979.

life-enhancing implications) but also amenable to the creation of explicit criteria. Pharmacy has a useful contribution to make here. An advantage of using quality of care criteria in the drug area is that application of such criteria provide a means of engaging the attending physician's attention and interest around a concrete area of care delivery in which educational interventions are likely to make an impact."

University of Minnesota

The University of Minnesota College of Pharmacy, under a contract with HEW, developed and field-tested drug utilization review guidelines for 10 drugs commonly used in the treatment of aged persons. These guidelines were developed with the advice and assistance of practicing physicians and other health professionals. The guidelines include model criteria which can be used as is or which can be modified as deemed appropriate by local physicians and other health professionals. HEW sponsored the development of these guidelines to assist SNFs in performing the medical care evaluation studies required by SNF regulations. HEW had 6,000 copies of the guideline published and said that most of the copies "* * * have been made available to pharmacists and nurses who work in nursing homes." (See app. VI.) In 1977, about 13,500 nursing homes were certified to provide care under the Medicaid program and another 5,400 homes were either certified for Medicare only or did not participate in either program. 1/

Patients were not tested in accordance with available criteria

Specific testing criteria on 10 of the 23 drugs included in our review were available from one or more of the five PSROs or from the drug utilization guidelines prepared by the University of Minnesota. The 10 drugs have been in use at least a decade and generally have a high usage by the

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1/The contract was awarded by HEW's Public Health Service, at a cost of $54,200. The guideline can be ordered from the Superintendent of Documents. The guideline is entitled "Drug Utilization Review in Skilled Nursing Facilities: A Manual System for Performing Sample Studies of Drug Utilization," U.S. Department of Health, Education, and Welfare, November 1975.

general population--5 ranked in the top 15 for volume of new and refill prescriptions by pharmacists nationwide in 1978. The 10 drugs were in one of four classes of drugs--diuretics (used to reduce body fluids), cardiac stimulants, hematinics (used to treat anemia), and antihypertensives (used to treat high blood pressure). The four classes of drugs are used in the treatment of many nursing home patients; a 1976 HEW report disclosed that the percentage of patients taking drugs in these classes ranged from 9 percent for hematinics to 29 percent for cardiac drugs.

The therapeutic role for each of the four drug classes and the reasons for monitoring them are discussed below.

Diuretics (6 drugs)

Diuretics are used to treat edema (an excessive accumulation of fluids in the body's tissues). Diuretics cause reduction of fluids in the tissues by increasing the excretion of fluids. A problem with diuretics is that blood serum electrolytes are excreted with the fluids, and this may cause blood electrolyte imbalance, which can adversely affect the functioning of the heart. Potassium is the electrolyte most likely to be affected by diuretics, and severe potassium imbalance (either too much or too little) can cause irregularities in the heartbeat, which can sometimes be fatal. Potassium loss can be dealt with by using a potassium-sparing diuretic or by offsetting the loss with extra potassium either in the diet or by taking potassium-supplementing medications.

Cardiac stimulants (1 drug)

Digoxin, the cardiac stimulant included in our review, affects the electrical conduction system of the heart. Digoxin, a digitalis preparation sold under the brand name of Lanoxin, tends to increase the muscular contraction of the heart, thus helping patients with congestive heart failure by increasing the heart's output of blood. The drug also delays the transmission of electrical impulses through the conduction system of the heart to restore normal heart rate and rhythm.

Digoxin has a narrow margin of safe use because it tends to accumulate in the blood and may reach toxic levels. The more serious consequences of digitalis intoxication are arrhythmia (irregularities of heart

rhythm) and heart blockage. Digitalis intoxication can also occur at otherwise tolerated dosage levels when the blood serum potassium level is below normal, indicating a need to closely monitor the patient's potassium level as well. Many patients treated for congestive heart failure take both digoxin and a diuretic. This can cause special problems, particularly if potassium-depleting diuretics are involved.

Hematinics (2 drugs)

Hematinics are drugs used to treat certain types of anemia. The drug increases the amount of iron containing pigments in the blood cells. The drugs should be monitored to determine whether the anemic condition is improving by use of hematinic therapy.

Antihypertensives (1 drug)

The antihypertensive drug we reviewed acts to relax constricted blood vessel walls and thus lower blood pressure.

Since not all the criteria sources recommended the same monitoring procedures for the 10 drugs, we used the most lenient criteria in analyzing the drug monitoring and testing of the sample patients. Specifically, we used the longest interval between tests as our minimum standard where sources differed as to frequency of a test, and we considered all tests where sources differed as to recommended tests. For example, while all PSROs specified that patients taking diuretics should receive electrolytes tests, the recommended frequency ranged from monthly to annually. We used as our criterion a 12-month test frequency. The specific criteria developed by each PSRO and the University of Minnesota, together with the criteria we used for each of the 10 drugs, are discussed in appendix II.

Using as criteria the drug monitoring recommendations made by the PSROs and the HEW-financed drug utilization guide, we reviewed the records of a sample of patients taking one or more of the 10 drugs. 1/ We obtained testing information

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1/We also reviewed the records of patients taking the other 13 drugs in our review. Testing frequencies for patients taking nine of these drugs are shown in appendix V. As discussed in appendix II (see p. 63), three of the other four drugs were dropped from the review because FDA indicated that tests were not necessary, and one drug was dropped because only one patient took the drug.

from the records of 349 Medicaid patients at 53 nursing homes 1/ in the five-State cluster and an additional 97 Medicaid patients in 14 nursing homes in California.

It should be noted that those patients we identified as not meeting drug screening criteria were not reviewed by an independent physician to determine whether exceptional circumstances were present which justified deviations from the criteria. On the other hand, as discussed starting on page 22, some of the PSROs also found, for some of the same drugs, high rates of noncompliance with screening criteria after the added step of physician peer review, which indicated deviations were not justified. Because the incidence of noncompliance with the screening criteria in our sample closely parallels, or was lower than, the incidence of noncompliance identified by the PSROs after peer review, we believe that our findings fairly reflect the general pattern of use of these 10 drugs in nursing homes in the five-State cluster.

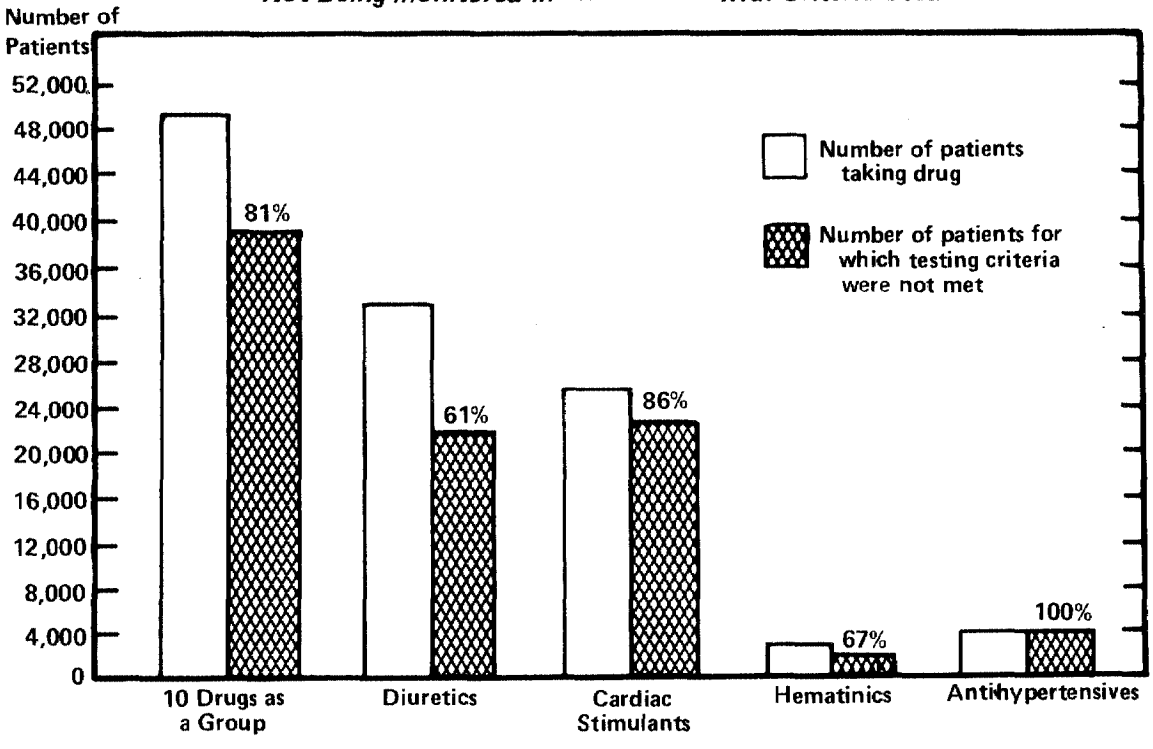
Of the 349 patients sampled in the five-State cluster, about 82 percent were not tested as frequently as recommended by the most lenient criteria available. (See app. III.) Using the sample results for the five-State cluster, we projected estimates of the total number of Medicaid nursing home patients in the five States who took these drugs and did not receive tests with the recommended frequency. 2/

As discussed in appendix I, we did not complete the sample in California, and the results shown cannot be projected with the data from the other five States. The projections for each of the four classes of drugs are shown in the following chart, and the projections for each of the 10 drugs are shown in appendix III.

1/We visited 54 nursing homes in the five-State cluster, but the patients reviewed in 1 home did not receive any of the 10 drugs.

2/The projection techniques included adjustments to assure that the weight given to sample results in each State were proportionate to that State's share of the total number of nursing homes in the five-State cluster. As a result, percentages based on raw data sometimes differ from percentages based on estimated data. For example, as noted above, 82 percent of the 349 patients in our sample were not tested as frequently as recommended; the corresponding estimate for the five-State cluster is 81 percent.

Projected Number of Medicaid Nursing Home Patients in the Five States Taking Each Class of Drug and Number Not Being Monitored in Accordance with Criteria Used



Some patients in our sample took more than one of the 10 drugs. As shown in the following table, there were instances when patients received tests with the recommended frequency for one drug but not for all drugs they took.

	Five-State cluster (Georgia, Iowa, Kansas, Massachusetts, and Texas)				California				
	Number of 10 drugs taken				Number of 10 drugs taken				
	1	2	3	Total	1	2	3	4	Total
Number of patients	230	112	7	349	59	34	3	1	97
Number of drugs on which criteria were met:									
None	176	62	2	240	40	14	1	1	56
1 of 2		42		42		17			17
1 of 3			3	3					
2 of 3			2	2			2		2
All	54	8	_	62	19	3	_	_	22
Total	230	112	7	349	59	34	3	1	97

As indicated above, most patients reviewed were not tested in accordance with the criteria we used. While some of these patients took the drugs for a long time within our review period--up to 26 months--and did not receive any tests, others received tests although not with the frequency recommended. For example, as shown in appendix IV, of the 238 patients 1/ who took diuretics, 149 received an appropriate test at least once while taking the drug. The 149 patients received a total of 1,062 tests. Some of the 149 patients were tested monthly, while others took the drug for more than 18 months before receiving a test. The other 89 patients received no tests although some patients had taken diuretics as long as 26 months.

When tests were performed, they sometimes resulted in a drug being discontinued or the drug dosage being adjusted. We noted 31 instances of drug discontinuance or dosage adjustment following tests on 22 patients taking the 10 drugs for which we had testing frequency recommendations. Following are four examples taken from patient files illustrating how tests can play a role in monitoring patient medications.

1/Twelve of the 238 patients took two diuretics. Therefore the sum of the numbers of patients shown in appendix IV as taking the various diuretics exceeds 238.

--A patient was taking two diuretics--Aldactone and Lasix--in January 1977. Aldactone is potassium-sparing and Lasix is potassium-depleting. On January 6, 1977, the patient received appropriate tests for this drug--an electrolyte battery (chlorides, potassium, and sodium). On January 14, 1977, the consultant pharmacist wrote a note that the laboratory tests showed the patient's potassium level was slightly high and the condition might be due to the diuretics. The note recommended that the nursing staff request the attending physician to review the medications. On January 17, 1977, the physician discontinued Aldactone.

--A patient began taking Lanoxin and a potassium-depleting diuretic in early July 1977. Potassium and digitalis level tests were made in September 1977, and the digitalis level test was repeated in early December 1977. In mid-May 1978 the patient was admitted to the hospital because of vomiting and digitalis intoxication with arrhythmia. While hospitalized, the patient was given various tests, including an electrocardiogram, digitalis level, and electrolytes, and the patient's daily dosage of Lanoxin was reduced by half from .25 mg to .125 mg. The patient was discharged from the hospital after 6 days and continued on the lower dosage.

--A patient had taken Trinsicon, a hematinic, for at least 4 months. In October 1976, the patient received a test for this drug and the drug was discontinued the same day.

--A patient was taking .25 mg of Lanoxin daily when he entered the nursing home in April 1977. On April 10, 1978, the patient received an electrolytes battery (chlorides, potassium, and sodium), an electrocardiogram, digitalis level tests, and kidney function tests. The electrocardiogram and digitalis level tests were repeated the following day, and Lanoxin was discontinued.

PSROs found drug-monitoring problems

We reviewed reports of results from long-term care evaluation demonstration projects of the Colorado and Utah PSROs. The Colorado PSRO's review covered 10 nursing homes,

and Utah's covered 15 to 20 nursing homes. 1/ We reviewed their findings with regard to the four drug classes discussed above. The PSROs established monitoring criteria for the tests and other procedures, such as taking the patient's blood pressure. The results discussed below represent those cases in which review by one or more independent physicians indicated that deviations from the criteria were not justified.

Diuretics

Both PSROs established as monitoring criteria electrolytes tests and weekly recording of each patient's weight and blood pressure. The following table shows the results of the PSRO demonstration projects along with the results of our five-State cluster sample for comparison.

Patients Reviewed Not Meeting Criteria

	Electrolytes tests at least every	Weight weekly	Blood pressure weekly
		(percent)	
Colorado PSRO	90 days	65	94	68
Utah PSRO	6 months	71-43	88-46	18-15
GAO	12 months	59	(a)	(a)

a/Not available.

The Colorado PSRO subsequently revised its electrolytes frequency criteria to once every 6 months. The compliance ranges shown for Utah represent the rates found in the early phase and the last phase of the demonstration project. Utah attributed the improvements in the later phase to physicians taking corrective action and otherwise adhering to PSRO criteria.

Cardiac stimulants

Neither the Colorado nor the Utah PSRO had developed specific criteria for monitoring digoxin by itself. However, the Utah PSRO made a special study to determine whether patients taking both digoxin and a potassium-depleting

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1/Fifteen of the original 20 nursing homes in Utah participated through the entire demonstration project.

diuretic received a potassium test at least every 3 months. The PSRO found that 77 percent of the patients (43 of 54) apparently did not receive potassium tests with the specified frequency. The PSRO notified the attending physicians of its findings. Not all physicians responded, but some who did said that tests had been done but not recorded in the patients' medical files.

In our five-State sample, 86 patients took digoxin and a potassium-depleting diuretic concurrently for at least a year. Fifty of the 86 patients (59 percent) had not received a potassium test at least every 12 months while taking both drugs. Our review included not only the patients' medical records but also State Medicaid agency vendor payment records. Therefore, we were able to identify tests that Medicaid paid for whether or not they were recorded in the patients' medical records.

Hematinics

Neither PSRO had demonstration results to report for hematinics, although the Colorado PSRO developed the testing criteria we used during the later phases of its demonstration project after it received information from physicians on its earlier criteria, which were not specific regarding frequency of test.

Antihypertensives

In its demonstration project, the Colorado PSRO found that about 66 percent of the patients taking antihypertensives did not have their blood pressure taken at least weekly. The Utah PSRO found that about 20 percent of the patients taking antihypertensives did not have their blood pressure taken either daily (if the patient's condition was unstable) or weekly (if the patient's condition was stable).

Both PSROs generally reported cases where criteria were not met to either nursing home officials or the attending physician. The Colorado PSRO did not formally assess the impact of its demonstration project but concluded that the result was increased compliance with the criteria based on informal feedback from nursing home officials and attending physicians. The Utah PSRO collected data at participating nursing homes on several occasions and generally found a higher rate of compliance with criteria in later phases of the data collection process at each facility. The PSRO attributed the increased rate of compliance to corrective

action being taken on those cases identified in earlier phases and to general acceptance of the criteria.

More information is needed about the use of multiple CNS-depressing drugs

In our second sample, we analyzed the medications taken by 212 patients in 30 nursing homes in four States and 95 patients in 14 nursing homes in California to determine whether the patients concurrently took multiple--and possibly excessive--numbers of drugs having the same therapeutic effect. One problem area we identified was the use of multiple drugs which depress the CNS.

CNS depressants generally work to block transmission of nerve impulses from the brain to the body's motor systems, such as the cardiac and respiratory systems. The mechanism by which different CNS depressants work varies, but normally at least one, if not all, of the body's motor systems are slowed down. This is of special concern in treating elderly and debilitated patients who are likely to have already experienced slowdowns in one or more body systems due to chronic illness(es) or the aging process or both.

When a person takes two CNS depressants, the depressant effect is usually greater than that of either taken alone. In some cases the drugs interact such that the combined depressant effect is even greater than the sum of the depressant effects of each drug taken alone. The problem with taking multiple CNS depressants is that the cumulative depressant effect may exceed the desired effect and the body's motor system activity becomes too slow.

A majority of nursing home patients take CNS-depressing drugs. A 1976 HEW report, 1/ for example, listed the major types of drugs taken by SNF patients. The list included types of drugs which depress the CNS as either a primary or a secondary effect (i.e., side effect). The report also estimated drug use in the Nation's SNFs. Among the more widely used types of drugs that can depress the CNS were pain relievers used by 51 percent of the patients, tranquilizers used by 47 percent, and sedative-hypnotics used by 35 percent.

1/"Physicians' Drug Prescribing Patterns in Skilled Nursing Facilities," June 1976. The report is based on a nationwide survey of 288 randomly selected SNFs.

Patients end up taking multiple CNS depressants for one or both of two reasons. First, some patients take more than one drug in the same category. For example, of the SNF patients discussed in the 1976 HEW report, a quarter of those who took tranquilizers took more than one tranquilizer. Second, patients sometimes take CNS-depressing drugs in more than one drug category. For example, a patient might take a tranquilizer, a pain reliever, and an antihistamine during the day and a sleeping pill at night.

Drug labeling for the CNS-depressing drugs we analyzed in this portion of our study normally contained little guidance concerning the use of more than one CNS depressant, other than the admonition to use caution.

The Colorado PSRO had established a guideline on the numbers of tranquilizers and sedatives to be taken concurrently. The PSRO categorized as "inappropriate utilization" taking three or more tranquilizers 1/ or sedatives in combination during the same day. The PSRO found in its demonstration project that almost 15 percent of the patients were receiving tranquilizers and sedatives in excess of its guidelines. The table below summarizes our findings applying the PSRO's guidelines to our sample population and the results of the PSRO's demonstration project.

Patients Taking Three or More Tranquilizers and/or Sedatives Except Compazine

Four-State cluster (Georgia, Iowa, Massachusetts, and Texas)		California		Colorado PSRO	
Number in sample	Percent	Number in sample	Percent	Number in sample	Percent
6 of 212	2.8	3 of 95	3.2	51 of 349	14.6

The nine patients we identified in our sample took these combinations of drugs daily for periods ranging from a month to a year and a half. One example is given on the following page.

1/The PSRO excepted one tranquilizer, Compazine, from this rule. We, therefore, also excepted Compazine in making our analysis.

A 79-year-old woman was in the nursing home for 22 months during our review period. In that time, she took nine different drugs that depress the CNS, including some drugs other than tranquilizers or sedatives. At any given time, she took anywhere from one to five of these drugs per day, although she usually took three. For a little over a year, she took Triavil (a combination of an antidepressant and a tranquilizer) twice a day, Phenobarbital (a barbiturate sedative) twice a day, and Dalmane (a nonbarbiturate sedative) once a day at bedtime. Over 6 months later, she was still taking Phenobarbital and Triavil when she also took the tranquilizers Haldol and Mellaril concurrently for a little over 2 weeks.

The Colorado PSRO also recommended that nursing home patients not receive more than 60 milligrams of Valium per week because of this CNS-depressing drug's extended half-life in geriatric patients. The labeling for Valium is less specific on dosage limitations:

> "In elderly and debilitated patients, it is recommended that the dosage be limited to the smallest effective amount to preclude the development of ataxia [1/] or oversedation (2 mg. to 2-1/2 mg. once or twice daily, initially, [14 to 35 mg. per week] to be increased gradually as needed and tolerated)."

Guidelines developed by the American Psychiatric Association, under contract to HEW, recommend that dosages of Valium for patients 65 years or older not exceed 140 milligrams per week. In our sample, 10 patients in the four-State cluster and 6 patients in California received in excess of 60 milligrams of Valium per week, with 5 of the 16 receiving 140 milligrams per week; however, none of the 16 patients received in excess of 140 milligrams per week.

Many drugs affect the CNS, and a majority of nursing home patients take one or more of them. We believe that more attention should be paid to various aspects of drug therapy

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1/Uncoordinated voluntary muscle action, particularly involving groups of muscles used in activities, such as walking or reaching for objects, caused by interference with the peripheral or CNS pathways involved in balancing muscle movements.

involving CNS-depressing drugs. The Colorado PSRO developed and field-tested guidelines for several aspects of managing CNS-depressing drugs. We believe that the Colorado PSRO's experience demonstrates the feasibility of establishing such guidelines.

Specific guidelines on contraindicated drugs not adhered to

In contrast to the lack of specific information in drug labeling regarding monitoring the long-term use of drugs and the concurrent use of multiple CNS-depressing drugs, drug labeling is often quite specific with regard to identification of contraindicated drugs. FDA defines contraindications to be "* * *those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." Our Chief Medical Advisor identified 13 cases of contraindicated drugs among the 212 patients (6.1 percent) in the four-State cluster and 2 more cases among the 95 patients in California.

The 15 cases of contraindications we identified involved six medical conditions (hypertension, cardiac dysfunction (all types), Parkinson's disease, glaucoma, ulcers, and senility and/or general debility) plus a known allergy to the drug. Three cases of contraindications involved more than one medical condition or more than one drug.

The 15 cases we identified were cases where the drug was contraindicated and there was no evidence the physician was using the drug in a life-threatening situation. The following is an example taken from the medical files we reviewed.

> A 75-year-old woman had a recorded diagnosis of glaucoma and a recorded history of allergic reactions to sulfonamides. She did not have a recorded diagnosis of recurring urinary tract infections, although it can be inferred from other information in her medical records. Her drug regimen included a number of drugs commonly used to treat urinary tract infections. During a 21-month period, she took Azo Gantrisin for 2 weeks, Gantrisin for 11 weeks and later again for 2 weeks, and Gantanol for a month; all three drugs are sulfonamides and the drug labeling for each specifically warns that allergic reactions are contraindicated. She also took Urised for 2 weeks concurrently with Gantrisin--Urised is contraindicated for patients with glaucoma. We found

nothing in her medical record to indicate why she was taking drugs that normally she should avoid, particularly in light of the fact that a number of other drugs which are neither sulfonamides nor contraindicated for glaucoma are available to treat urinary tract infections.

RECENT DEVELOPMENTS LEADING TO A SINGLE AUTHORITATIVE SOURCE OF DRUG INFORMATION

HEW has recently taken action to improve drug labeling information, which it considers an important step in developing a drug compendium. Legislation has been introduced which includes provisions for developing a drug compendium, 1/ but the results of these actions will not be available for several years. As an interim measure, HEW could compile existing guidelines for use by medication reviewers, pending publication of a drug compendium. Also, the guidelines should be of immediate value to FDA's drug labeling improvement program and in the eventual development of a drug compendium.

FDA actions to improve drug labeling

In 1978, the Commissioner of FDA stated that the agency had been in favor of a drug compendium for nearly a decade. He said that a major problem in developing a compendium has been a lack of uniform labeling needed for complete and accepted drug descriptions. In June 1979, FDA issued final regulations 2/ which designate a required labeling format and provide standards for the information that must appear in each section of that format. FDA considers the regulations to be an important step in developing data needed for a drug compendium. The regulations specify the following with regard to laboratory tests.

> "Laboratory tests: This subsection of the labeling shall identify any laboratory tests that may be helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information shall be provided on

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1/H.R. 4258, S. 1045, and S. 1075. (See p. 31 for a discussion of these bills.)

2/The proposed regulations were issued in April 1975.

such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be done before, during, and after therapy." (21 CFR 201.57(f)(3)) 1/

Drug manufacturers will be required to revise labeling for drugs already on the market--including the drugs in our review--in accordance with a timetable to be established by FDA. This timetable had not been published as of March 1980. FDA officials expect the revisions to take several years. The extent of the benefits from this new regulation, therefore, will not be known for some time. Also, improvements in the labeling of individual drugs probably will not provide the specific guidelines needed where multiple drugs are involved, such as in the CNS depressants previously discussed. (See p. 25.) In our opinion, the types of guidelines needed can best be provided in a document with broader scope, such as a compendium which includes specific guidance on the use of multiple drugs in the same therapeutic category or affecting the same body system.

In commenting on a draft of this report, HEW stated that it is impossible to address in labeling or a compendium the myriad combinations and permutations that are possible with the number of drugs presently available because of the immense expenditure of resources which would be required to determine the effects produced by all the possible drug interactions and develop specific labeling. HEW stated that FDA already requires appropriate warnings on the labeling in situations where it has reason to believe that certain drug combinations will produce adverse effects. We realize that a massive number of drug combinations are possible; however, as we discuss on page 32, nursing home patients normally take a relatively small number of distinctly different drugs. Therefore, we believe that HEW is overstating the difficulties it would face in gathering criteria already developed by PSROs on drugs and drug combinations already identified as being those most often used by geriatric patients in nursing homes.

1/The proposed regulations did not mention laboratory test frequency. FDA added this on the basis of comments received from the public during the comment period following the 1975 issuance of the proposed regulations.

According to HEW, drug labeling is intended to be used in the context of medically informed professionals exercising judgments concerning individual patients who have unique health conditions and drug responses, and a majority of approved drug labeling is adequate in that context. HEW therefore opposes establishing any drug monitoring criteria which would be rigidly applied without benefit of the judgment of skilled professionals as to whether circumstances applicable to individual patients justified deviations from those criteria. APhA and the Colorado PSRO take similar positions.

The drug information we proposed be disseminated is screening criteria, and we agree that a final decision on the need to adhere to those criteria should rest with a physician. While, as HEW contends, drug labeling may generally be adequate for physicians, we believe that more specific criteria are needed by pharmacists and nurses in order to adequately perform medication reviews.

HEW also stated that some drug interaction information is available from various sources, such as texts, and questions whether it is realistic or desirable to expect that all information about drugs will ever be available from one source. We believe it is unreasonable to assume that nursing homes will maintain extensive libraries of drug reference material, such as texts and clinical journals, or that it is even possible for the homes to gather this information, considering the multiplicity of sources. We therefore believe that it is incumbent upon HEW to gather and disseminate drug information, including screening criteria. While, as HEW contends, it may not be realistic to expect that all information about drugs will ever be contained in one source, we believe that important information which may not be appropriate or practical to include in labeling should be disseminated to nursing homes and that a drug compendium is a logical vehicle for doing so.

Proposed legislation
authorizing a drug compendium

In 1979, legislation was introduced in the Congress which would authorize the Secretary of HEW or a private

organization to develop a comprehensive drug guide. 1/ The provisions of the bills are similar in that drugs would be listed by diagnostic and therapeutic categories and the information on each drug product would be listed according to guidelines specified by the legislation and the Secretary of HEW.

Development of the drug guide, if legislation is enacted, will be a formidable task, taking several years to complete. About 5,000 prescription drug products had FDA marketing approval as of December 1979.

HEW can expedite dissemination of drug guidelines for nursing home patients

Because FDA's drug labeling improvement program and the development of a drug compendium will take several years to complete, HEW has the responsibility for issuing, as an interim measure, drug guidelines which would be of use to nursing home pharmacists and registered nurses in discharging their medication review responsibilities. Moreover, the guidelines, using the information developed by PSROs and others (see p. 13), should be of immediate value to FDA in its drug labeling improvement program and in developing a drug compendium because they provide specific drug information on a large and easily identified drug-user population, based on actual clinical use in thousands of nursing homes nationwide.

While there are about 5,000 prescription drugs having FDA marketing approval, the number of drugs taken by nursing home patients is considerably smaller--no more than 500, according to various studies. The number of distinctly different drugs is less because some apparently different drugs are actually the same drug under different names. For example, our analysis of drugs taken by nursing home patients

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1/Section 155 of H.R. 4258 and S. 1045 require that the Secretary of HEW prepare and publish a Federal Drug Compendium. Section 117 of S. 1075 provides for issuance of a Federal Drug Index, and private sources would be granted 3 years to publish the document in accordance with requirements established by the bill and by the Secretary of HEW. If a satisfactory index had not been published at the end of 3 years, the Secretary of HEW would be authorized to assume responsibility for having the index prepared and published.

showed that some patients were taking the generic drug hydrochlorothiazide, while others were taking one of its several brand name versions. One of the brand names was Hydrodiuril--a diuretic for which we identified specific drug monitoring criteria. (See p. 64.) The criteria apply to hydrochlorothiazide regardless of the name under which it is sold. We estimate based on our sample that 1 or more of the 10 brand-name drugs in our review were taken by 31 percent of the nursing home patients in the five-State cluster. The estimate is based on patients taking only the 10 brand-name drugs and does not include patients taking the drugs under other names.

Some drug criteria developed by PSROs are based on drug classes rather than individual drugs, thus reducing the potential workload in developing drug guidelines. For example, the five PSROs developed criteria for diuretics as a drug class rather than by brand or generic name. Most drugs taken by nursing home patients are in relatively few classes of drugs. The following table from a 1976 HEW report shows the classes of drugs which were taken by 15 percent or more of nursing home patients.

Drug class	Percent of nursing home patients taking at least one drug in the drug class
Laxatives	58
Analgesics	51
Tranquilizers	47
Sedatives or hypnotics	35
Vitamins	34
Cardiac drugs	29
Diuretics	23
Skin and mucous membrane	20
Antihypertensives	a/18
Anti-infectives	16

a/Includes patients taking two generic drugs categorized in this report as diuretics (Diuril-chlorothiazide and Hydrodiuril-hydrochlorothiazide).

As discussed in this chapter, PSROs and the University of Minnesota have developed screening criteria on the monitoring and use of drugs or classes of drugs shown in the above table. They had developed some criteria on the 10 drugs in four drug classes (cardiac stimulants, diuretics, antihypertensives, and hematinics) in our review. The PSROs and

the University of Minnesota have also developed criteria on some of the other classes of drugs shown above. The Colorado PSRO developed guidelines on the concurrent use of tranquilizers and sedatives as a class, and the University of Minnesota developed guidelines for use of one specific tranquilizer and a nonprescription laxative.

PSROs are an important resource to HEW in the development of monitoring guidelines for nursing home patients. The criteria are developed by practicing physicians and other health professionals, tested in the field, and revised where appropriate. For example, the Colorado PSRO began its demonstration project recommending certain tests to monitor hematinic therapy but without specifying the frequency of the tests. By the end of the demonstration project, the PSRO had established a monitoring frequency of not less than once every 6 months.

Although the drug criteria developed to date by PSROs have not been widely disseminated, review, validation, and acceptance of the criteria by the medical community at large can be expedited through the National Professional Standards Review Council, which has criteria development and review as a major function.

We believe that HEW should collect and evaluate the drug criteria that have been developed to date by PSROs and by others under HEW contracts, send those criteria it considers to have merit to all U.S. nursing homes, and periodically revise and enlarge the scope of this interim document as PSROs and others gain more experience in monitoring the medications of nursing home patients.

Concerning drug criteria, HEW said in its comments on a draft of this report:

> "Distributing criteria has merit if they are considered useful by the reviewers and accepted by the physician. * * * HEW is in the process of contracting for the development of sample criteria for long-term care generally and we expect that contract to result in the development of sample drug criteria."

HEW agreed to involve the National Professional Standards Review Council in promoting drug monitoring criteria development but made no mention of the use of these criteria by FDA in its efforts to improve prescription drug labeling.

APhA endorses the distribution of PSRO criteria as an educational tool with the stipulation that the criteria not be treated as enforceable standards and that they be subject to modification to meet local needs and conditions. The Colorado PSRO does not support distribution of criteria if this information would constitute national standards in which deviations from standards would not be evaluated by peer (i.e., physician) review.

CHAPTER 3

HEW HAS NOT PROVIDED ADEQUATE MEDICATION REVIEW GUIDELINES TO PHARMACISTS AND NURSES

Quality drug therapy for nursing home patients requires the combined talents of three professions--medicine, pharmacy, and nursing. The three disciplines strive to assure that:

--The right drug is prescribed for the patient's condition.

--The drug is administered to the right patient in the right dose at the right time.

--The drug achieves its desired effect.

--It does so without resulting in significant adverse effects.

Only the physician can prescribe drugs for nursing home patients. HEW, however, requires that nursing homes have a pharmacist or registered nurse review the medications of each patient monthly. Although the Federal regulations require medication reviews, HEW has not adequately defined the scope of medication review--such matters as reviewing a patient's medical records, observing and interviewing the patient, and determining whether specific types of potential problems exist. In the absence of a definition of the scope of medication review, the individual pharmacists and registered nurses are left to develop their own interpretations of what should be done.

Our discussions with pharmacists and registered nurses engaged in medication reviews at the nursing homes we visited showed that the scope of their reviews varied. We were unable to draw conclusions as to the adequacy of these reviews because HEW has not established minimum standards as to scope of review. To ensure that the scope of medication review is adequate, HEW needs to establish such standards. HEW also needs to assure that training is available to medication reviewers to orient them as to the various metholodogies which can be used to perform medication reviews.

Many pharmacists were serving patients as both drug dispenser and medication reviewer, creating a potential conflict of interest. Although we found no evidence that pharmacists were not objective in their reviews, we believe that separating these two functions provides for better control in that the pharmacist is not placed in a potential conflict-of-interest situation.

MEDICATION REVIEWERS HAVE NOT RECEIVED ADEQUATE GUIDANCE FROM HEW

The HEW regulations requiring medication review are vague as to the scope of a satisfactory medication review, leaving pharmacists and registered nurses to develop their own interpretations as to what should be covered. Although HEW did not clearly define scope of review, which we believe should have been the first step, it has provided some support for development of, and training in, some review methodoligies. However, the extent of the unmet need for training is not known.

Required scope of medication review is vague

HEW has required medication review since the nursing home regulations were first issued. However, it has never defined the scope of these reviews. Medicare SNF regulations, first issued in October 1967, required the prescribing physician and registered nurse to jointly review each patient's medications monthly. Medicaid SNF regulations, first issued in June 1969, adopted the same requirements. In 1974 HEW issued uniform regulations for the Medicare-Medicaid SNF program and the first regulations for the Medicaid ICF program.

HEW's regulation on medication review in SNFs, issued in 1974 and still in effect, states:

> "The pharmacist reviews the drug regimen of each patient at least monthly, and reports any irregularities to the medical director and administrator."

HEW's regulation on medication review in ICFs, also issued in 1974 and still in effect, states:

> "A registered nurse must review medications monthly for each resident and notify the physician if changes are appropriate."

Regulations of two of the States in our review provided some guidance to medication reviewers as to scope of review. California SNF regulations state that the pharmacist's review shall include all drugs currently authorized for the patient, information concerning the patient's condition relating to drug therapy, medication administration records, and where appropriate, physicians' progress notes, nurses' notes, and laboratory test results. Iowa ICF regulations state that the nurses' review shall include procedures of administration, recording of medication, possible drug reactions and interactions, and followup of medication errors.

HEW may revise the ICF regulations to require medication review by a pharmacist. This action is being considered because pharmacists have conducted several medication review studies and reported success in reducing the number of drugs patients take, and because it would give registered nurses additional time for nursing duties.

Two of the six States we visited require pharmacists to review ICF patient medications. Kansas revised its regulations in 1977 to require a quarterly review of ICF patient medications by a pharmacist in addition to the monthly review by a registered nurse. The change was made to provide additional protection to patients, particularly in assuring that the patient does not receive combinations of drugs that may cause undesirable interactions. Texas revised its regulations in 1978 to require a monthly review of ICF patient medications by a pharmacist whether the patient's care is paid for by Medicaid or not. The change was made primarily to eliminate confusion as to whether a pharmacist or nurse was responsible for reviewing medications.

Reports indicated pharmacists needed training and guidelines

The American Association of Colleges of Pharmacy, in a 1975 report (see p. 9), stated that there was no universally accepted definition of either clinical pharmacy or the knowledge, skills, and roles involved. There was, however, general agreement that the concept dealt with drugs as they are used by, and in, the patient. The report went on to suggest there was an unmet need for schools of pharmacy to offer additional training for specialty types of practice, such as clinical pharmacy in the nursing home, to supplement the basic knowledge of drugs common to all pharmacists.

HEW, in a 1975 report, stated that pharmacists were experiencing problems in developing appropriate review methodologies. This statement was based on observations of an HEW task force that visited and reviewed care in 288 randomly selected SNFs nationwide in 1974. 1/ The task force's findings included the following regarding patient medications and pharmacists' services:

--Multiple drug prescribing for individual patients was the prevailing pattern, including combinations of drugs which commonly present hazards to patients.

--Patient medications were often selected to alleviate symptoms of illness rather than selecting drugs that might have a direct therapeutic action on the underlying cause of the disease.

--Many pharmacists were using patient drug profile records to monitor the drug therapy. While the records usually included such information as the name of the drug and date the prescription was filled, it often did not contain information which would help the pharmacist in monitoring drug therapy, such as drug sensitivities and chronic diseases.

--Many pharmacists were spending less than 5 hours per week in providing pharmaceutical services, raising questions as to the effectiveness of the services.

While the report did not make any recommendations regarding training in medication review, it did state that training such as that discussed below would enhance pharmacists' skills in reviewing drug regimens and in interacting with nursing and medical personnel as part of their review activities.

APhA guidelines were not fully used

APhA, a national society of pharmacists, under contracts with the Public Health Service, conducted a series of workshops and developed training materials which included medication review. The contracts were awarded starting in mid-1973 as part of HEW's program to improve the standards and quality

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1/The Long Term Care Facility Improvement Study was coordinated by the Office of Nursing Home Affairs, Assistant Secretary for Health, although representatives of many HEW agencies participated.

of nursing home care by providing short-term training courses for personnel who are regularly involved in furnishing services to nursing home patients. The nursing home improvement program 1/ had been initiated in 1971 at the direction of President Nixon. The contract justification documents include the following statement:

> "There is currently a need for the pharmacy profession to take strides to improve drug distribution techniques and clinical services in the nursing home environment. Many pharmacy practitioners in nursing homes lack adequate training for the tasks which they are required to perform. While they may have had extensive training in general pharmacology, it is unusual for them to have had specialized training on how drugs affect elderly persons. The activities described in this proposal will provide them with this much needed specialized training and will encourage colleges of pharmacy to institute an ongoing program to educate students to the unique pharmaceutical needs of the institutionalized geriatric patient."

The scope of the APhA work included (1) conducting a series of workshops and seminars on institutional pharmaceutical services, including medication review, (2) preparing a curriculum for schools of pharmacy to provide similar training to students, (3) developing and promoting a home study course for pharmacists on monitoring drug therapy, and (4) developing and promoting a teaching guide for use by pharmacists in training nursing home staffs in pharmacy services. The total cost of the contracts was about $90,000.

APhA officials told us that their organization had also invested in the project and that its efforts had exceeded contract requirements. For example, while the contract specified 20 workshops, APhA participated with State and local organizations in about 60 workshops and related

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1/The Public Health Service was responsible for the nursing home improvement program and awarded the contracts to APhA. Nursing home standards were established at that time by the Social Security Administration (Medicare) and the Social and Rehabilitation Service (Medicaid). Medicare and Medicaid functions were placed under HCFA when it was established in 1977.

activities between May 1974 and July 1975. About 4,600 persons attended the workshops, including pharmacists, nurses, physicians, and nursing home administrators. APhA was unable to estimate total workshop enrollment because some State and local organizations have continued the program; however, officials said they have distributed about 16,000 workbooks to workshop sponsors, pharmacy schools, and individual pharmacists.

The model curriculum was transmitted to all pharmacy schools in 1976. The pharmacist home study course was published in 1978, and about 1,000 had been sold as of January 1980. The teaching guide for pharmacists was published in 1977, and about 2,200 had been sold as of January 1980.

Neither APhA nor HEW knows how many pharmacists or nurses involved in medication review have been exposed to the training courses or materials.

LACK OF UNIFORMITY IN SCOPE OF MEDICATION REVIEW PROCEDURES

We interviewed pharmacists and registered nurses to determine the scope of coverage in their medication reviews. Lacking minimum scope standards from HEW, we compared the pharmacists' descriptions of review coverage to the scope implied in APhA's training materials. In our opinion, the scope of reviews by some pharmacists was generally less comprehensive. The scope of review by nurses also varied; however, their reviews were in addition to those being made by pharmacists.

APhA medication review guidelines

The APhA medication review training materials included specific review methodology. According to APhA, the purpose of this material was to orient pharmacists and others to the medication review process, the set of procedures outlined are neither standardized nor required in all instances, and there can be many other sets of equally satisfactory review procedures. While recognizing that the procedures prepared by APhA do not constitute the only acceptable methodology, we believe that the materials imply certain minimum coverage which can reasonably be expected of the reviewer regardless of specific procedures followed. The APhA training materials indicate that the scope of medication review made by pharmacists should include:

--Reviewing the patient's medical records. This review should include physicians' orders and progress notes, medication sheets, nurses' notes, lab test reports, and hospital discharge summaries. In reviewing these records, the pharmacist should examine vital signs data (pulse, respiration, and blood pressure), laboratory test results, diagnoses, observations recorded by the nursing staff and others, and recorded statements of the patient (e.g., complaints).

--Observing and interviewing the patient, at least in cases where analysis of the medical file indicates a problem possibly caused by a drug or drugs.

--Taking appropriate action where medication problems are identified. If the safety of the patient is at risk, the pharmacist should contact the physician, nursing staff, and administrator to assure immediate corrective action. If there is no immediate danger to the patient's well-being, the pharmacist may either notify the physician or nursing personnel or make an appropriate entry in the patient file. The pharmacist should also document the corrective action taken and follow up on the patient's problem to assess the results.

In analyzing each patient's medications, the pharmacist should determine whether:

--Each drug is administered as ordered by a physician.

--Each drug administered is supported by a diagnosis, condition, or symptom.

--The drug being administered for each ailment is the drug of choice.

--The dosage strength of each drug being administered is appropriate, given the patient's age, chronic and present disease(s), and current general health.

--Duplicate medications are being administered.

--Potential causes of adverse effects exist, such as drug-drug, drug-food, or drug-disease interactions or hypersensitivity potential.

--Evidence of adverse effects is present and, if so, whether these effects are being controlled within tolerable limits.

--Appropriate tests have been ordered and made.

--Each drug administered is achieving the desired effect.

It is not clear whether the scope of medication review expected of a registered nurse is as comprehensive as that of a pharmacist. However, APhA guidelines for training the nursing staff indicate the nurses' responsibility to be as follows:

--Assuring that medications are administered as prescribed.

--Assuring that monitoring procedures to avoid possible drug reactions are carried out.

--Watching for signs of possible adverse effects and evidence that the desired therapeutic response is being achieved.

According to these guidelines, the nursing staff generally is not expected to render an opinion as to whether each drug taken by a patient is necessary and whether the drugs being used are the best for the patient's condition(s) under treatment.

Scope of medication review varies

We interviewed 50 registered nurses and 54 pharmacists who had medication review responsibilities at 62 of the 68 nursing homes we visited. We asked each pharmacist and nurse to describe what he or she did in the way of reviewing patient medications.

The review procedure cited most frequently by registered nurses was determining whether each patient's drugs were administered in accordance with the physician's orders. Some nurses said their review included consideration of other matters, such as need for tests or the physician's choice of drugs, while others said that these matters were reviewed by the pharmacist or attending physician. Pharmacists were also reviewing medications at 47 of the 50 nursing homes

where nurses described their medication review procedures. Nurses at the other three homes reviewed medications with the attending physician. Consequently, the scope of review by the 50 nurses may not be representative of reviews in nursing homes where nurses have sole responsibility for medication review.

While the scope of review described by the pharmacists we interviewed generally agreed with the scope shown on pages 41-43, some pharmacists were deviating in important aspects. For example:

--Eight pharmacists did not review patient medical records or did not do so routinely.

--Sixteen pharmacists routinely reviewed patient medical records, but 13 did not study the drug regimen in order to make recommendations about the need for tests or the physician's choice of drugs and the other 3 studied the drug regimens but did not always make the recommendations they believed were warranted.

We asked the 24 pharmacists why the scope of their medication reviews did not include the above. Their comments generally could be placed in the following categories: (1) their perceived inability to analyze certain aspects of patient medications, (2) their personal concept of what a medication review should consist of, including their understanding the extent of their authority and responsibility, and (3) their relationships with physicians treating the patients.

Perceived inability

Eight pharmacists told us they were unable to perform all aspects of medication review, and three of them did not explain why. One pharmacist, citing a lack of adequate drug information, told us he believes that tests are not performed often enough, but was not sure what the frequency should be. Another said that he would have to do considerable research before he would question a physician's choice of drugs because he, and three other pharmacists, considered nurses or physicians to be better qualified in certain aspects of medication review.

Pharmacists and registered nurses generally rely on their personal drug knowledge, which is based on their education, training, and experience. The most frequently cited drug reference sources were drug labeling and the Physicians' Desk

Reference. As discussed in chapter 2, these sources do not always provide adequate information on the monitoring or use of drugs.

Concept of medication review

Nine pharmacists expressed doubts about the adequacy of the scope of their reviews. Three pharmacists told us that they needed more specific guidelines. One pharmacist told us that she had not been aware of the need to screen for tests until she attended a medication review workshop. Other pharmacists believed that certain aspects of medication review, such as need for tests or choice of drugs, were "not my job"--without explaining why--or were the responsibility of nurses or physicians. Another pharmacist felt that making recommendations was inappropriate because it would constitute telling the physicians how to practice medicine.

Relationships with physicians

Eight pharmacists said they either do not make recommendations regarding certain aspects of drug therapy or do so selectively because of possible resentment by attending physicians. For example, one pharmacist said he thinks that about 75 percent of the patients in the home he serves need tests but has been reluctant to recommend them because of what he characterized as the physician's "resentful attitude." Another pharmacist stated that, before deciding whether to recommend tests, he considers who the attending physician is, the seriousness of the condition, and the number of recommendations he has made on that physician's patients during his most recent reviews.

We received varying opinions on the value of the pharmacist's medication review from 15 attending physicians, including 9 who served as SNF medical directors. Of the six physicians who served only in an attending capacity, three said they felt the pharmacists' reviews were unnecessary because the pharmacists had not made any contributions and that pharmacists were not qualified to question their judgments. Another attending physician said he was unaware that a pharmacist was reviewing his patients' medications. All nine SNF medical directors said that the pharmacists were conducting adequate reviews, although three thought the review was unnecessary because physicians are more knowledgeable about drugs and patients or because physicians should be trusted.

We identified another problem area that appears to involve, at least in part, relationships with physicians--following up on a recommendation which was made but not followed. Nine of the 54 pharmacists discussed the matter of followup, and 6 of them told us they generally did not assure themselves that recommendations that were not followed had, in fact, been brought to the attention of the physician. We noted one nursing home where the director of nursing screens the recommendations before deciding which ones to pass on to the physicians.

The need for cooperation by the medical profession to have a successful medication review program was identified by the HEW task force in the 1974 study of long-term care problems in SNFs. One conclusion of this study was that the pharmacists' reviews of medication held great promise for improving the monitoring of drug therapy but would require diligent application of the pharmacists' knowledge and the cooperation of, and coordination with, the nursing and medical professions in order for the review to benefit the patient.

We believe that development and dissemination of drug utilization guidelines (and eventually a drug compendium) and minimum standards for scope of coverage in medication review should alleviate pharmacists' and nurses' concerns discussed above and give them a clearer understanding of their roles and responsibilities. While issuance of these guidelines will not solve all problems in their relationships with physicians, medication reviewers may be less reluctant to make recommendations when they are guided by authoritative drug information and a well-defined role.

We believe that HEW should establish minimum standards as to the scope of medication review and also assure that medication reviewers are apprised of review methodology. Both HEW and APhA have stated that they are opposed to any standards which would require reviewers to follow a certain system regarding method of review. APhA agreed that HEW should do more to apprise nursing homes and health care personnel of the many possible elements of a medication review. We concur with HEW and APhA that reviewers should not be required to follow a certain system or method; however, we believe that HEW can define the scope of medication review coverage while still allowing reviewers the latitude to choose specific review procedures to be followed.

STATE AGENCIES GENERALLY DO NOT EVALUATE MEDICATION REVIEWS

Federal regulations require the States annually to make at least two types of inspections at nursing homes participating in the Medicaid program--a survey of the home's compliance with State and Federal regulations by the State licensing agency and a medical review of each patient by the State Medicaid agency, unless this latter function has been taken over by PSROs. Because both agencies have nursing home oversight responsibilities, we determined whether either agency was evaluating medication reviews. The regulations mandating these State licensing and Medicaid agency inspections and the accompanying guidelines do not require the State inspection teams to evaluate the medication reviews performed by nursing home pharmacists and nurses. Such State evaluations generally were not being made in the six States included in our review.

Oversight role of State agencies

HEW regulations require that State agencies perform certain functions in the Medicaid nursing home program. The agencies involved and their roles are as follows.

State licensing agencies

The State agency responsible for licensing nursing homes must visit and survey each nursing home participating in Medicaid at least anually and either certify that the facility is in compliance with Federal and State regulations for the types of care (e.g., skilled, intermediate) being provided or has a satisfactory plan for achieving compliance. Nursing homes failing to obtain this certification cannot participate in the Medicaid program. An agency survey team must review at least a sample of medical records to determine that, among other things, the nursing home's consultant pharmacist or registered nurse has performed the required monthly medication review. The applicable HEW guidelines state that the survey team's review comments should include a statement that the medication reviews were made and whether irregularities were found, recommendations made, and corrective action taken.

State Medicaid agencies

As part of its utilization control program, the State Medicaid agency is required to make, or have made, at least

annual onsite inspections at each facility during which the care of each Medicaid patient is reviewed and evaluated. These evaluations are called medical reviews. The inspection teams must include a registered nurse or physician and other appropriate health and social service personnel. A physician must be available to consult with the team as needed, if not a member of the team. The teams are required to review each Medicaid patient's medical records and to have personal contact with, and observe, each patient. Regulations and guidelines for State Medicaid agencies do not specifically require medical review teams to review patient medications, although it is implied in that they are charged with evaluating patient care, which would include drug therapy.

PSROs are gradually assuming State utilization control functions, including medical reviews, in SNFs. State Medicaid agencies will continue to review Medicaid ICF patients unless (1) the State requests the PSRO to assume responsibility, (2) HEW finds that the State agency is not performing effective reviews, or (3) HEW finds that, in nursing homes which have both SNF and ICF patients, it is "inefficient" for the PSRO and the State agency to split the review responsibility.

State inspectors generally did not evaluate medication reviews

We interviewed State Medicaid agency medical review team members and State licensing agency survey team members and found, in general, that they faced much the same problems that registered nurses and pharmacists faced in performing monthly medication reviews--lack of a single authoritative source of information on drug use and monitoring and lack of a clear definition of the scope of medication review.

We reviewed licensing agency survey reports on all 68 homes we visited and Medicaid agency medical review reports on 67 homes. Because the reports did not always contain detailed information, it was difficult to determine the extent of any medication-related deficiencies found by either type of team. Also, some team members said that questions they raised on patient medications were not always included in the reports. The most frequently cited deficiencies in the reports were problems with drug storage and custody, administration of drugs, and charting--all of which can be characterized as nursing home-related deficiencies rather than medication-related deficiencies.

Reports for 16 homes included cases in which patients did not receive tests that team members thought should have been made. Reports for 10 of the 16 homes either did not contain sufficient detail to indicate why the tests were needed or indicated the tests were not related to medications. Reports for 6 of the 16 homes cited cases in which tests were needed in conjunction with medications. The tests cited as needed included blood clotting tests for patients taking blood-thinning drugs and electrolytes tests for patients taking diuretics.

The reports show the inconsistencies inherent in application of team members' personalized drug monitoring criteria. Some team members, particularily those on medical review teams, said that, in reviewing patient medications, they generally relied on their personal drug knowledge. Patients in all six homes we visited in Iowa were receiving diuretics, and some patients in each home were not receiving electrolytes tests. The medical review reports for only two of these homes, however, said that patients on diuretics were not being given periodic electrolytes tests. Both homes had been inspected by the same nurse, who told us that her belief that tests should have been performed was based on her experience working with physicians.

Reports on 3 of the 68 homes we visited questioned the adequacy of medication review, but in our opinion, the exceptions taken were not based on indepth assessments. The three homes were cited for the following problems:

--The registered nurse's medication review was considered inadequate by the medical review team, because she found no medication irregularities in a 6-month period.

--The registered nurse's medication review was considered inadequate by the survey team, because the nurse should have identified inactive drug orders and requested the attending physicians to cancel them.

--The pharmacist was not spending enough time in medication review, because the survey team found numerous drug charting errors.

As noted above, the deficiencies most frequently cited in the inspection reports we reviewed were nursing home-related deficiencies, such as errors in drug administration. HEW has proposed revisions in the conditions of participation for SNFs and ICFs to deal with these nursing home-related deficiencies. (See app. VI.)

We observed little activity by State inspectors in evaluating medication reviews. Part of this can be attributed to the lack of a requirement that such evaluations be made. However, part can also be attributed to the same problems facing registered nurses and pharmacists making monthly medication reviews at nursing homes--lack of a single authoritative source of drug information and lack of a clear definition of the scope of medication review.

PHARMACISTS REVIEWING MEDICATIONS HAVE POTENTIAL CONFLICTING INTERESTS

Pharmacists provide to nursing homes services other than medication review. If a nursing home does not have a staff pharmacist, it is required to retain a pharmacist under a consultant agreement. The consultant agreement must be in writing and set out functions, objectives, and terms of employment. HEW considers the consultant's fee to be an allowable cost in determining the nursing home's reimbursement rate.

Federal SNF regulations require that the pharmacist's duties and responsibilities, other than medication review, include the following:

--Being responsible to the administrative staff for developing, coordinating, and supervising all pharmaceutical services.

--Submitting a written report at least quarterly on the status of the facility's pharmaceutical service and staff performance.

--If not a full-time employee, devoting enough hours, based upon needs of the facility, during regularly scheduled visits, to carry out these responsibilities.

ICF regulations require that a licensed pharmacist provide consultation on methods and procedures for ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

Under Federal regulations, payments for prescriptions are the lower of (1) the pharmacy's acquisition cost of the drug plus a dispensing fee established by the State or (2) the pharmacy's usual and customary charge to the public.

Under either payment system, the pharmacy's profit is tied to the drugs sold, thus creating a financial incentive to not recommend to prescribing physicians the elimination of unnecessary drugs. We believe that pharmacists involved in both medication review and selling drugs to patients have potential conflicting interests and, therefore, the integrity of the reviews may be subject to question. Executive Order 11222, which prescribes standards of ethical conduct for officers and employees of the Federal Government, defines potential conflict of interest to include situations where an individual, because of financial or other interests, could lose, or create the appearance of losing, complete independence or impartiality of action. Although the order is not applicable in this situation, the principle involved is identical.

At 40 of the 68 nursing homes in our review, the pharmacist serving as consultant and reviewing patient medications was also associated with the retail pharmacy providing drugs to many patients residing in that facility. In 37 of the 40 cases, at least one other retail pharmacy was available in the community where either the nursing home or the vendor/consultant was located. While we found no evidence that the pharmacists were not objective in their review, the situation discussed above creates the appearance of a potential conflict of interest.

In June 1977, HEW issued to State Medicaid agencies draft revised guidelines covering payment for both prescription drugs and pharmacy consultant services. The guidelines said, in part, that in geographic areas where it is possible and feasible, separation of pharmacy consultant services and drug vendor services is encouraged. The guidelines, however, have never been issued in final form because of unresolved issues regarding reimbursement for the costs of filling prescriptions. In our opinion, HEW should issue regulations requiring separation of the medication review component of consultant services from drug vendor services whenever feasible and deal separately with regulations regarding reimbursement for the costs of filling prescriptions.

HEW stated that, while it shared our concern about a potential conflict of interest, it believed "that regulations should be instituted only if there is evidence of actual harm to patients." HEW also stated that separation of the two functions would, because of inadequate reimbursement for drug regimen reviews, seriously limit the ability of nursing

homes to secure any meaningful review of records. According to HEW, reimbursement for dispensing services are supporting, to a large degree, the drug regimen review activity.

HEW's policy of encouraging pharmacists to subsidize the medication review cost from their dispensing fees was included in matters discussed at congressional hearings held in March 1977. 1/ At those hearings, an APhA representative criticized this practice. According to him, to expect the pharmacist to support both dispensing and nondispensing services on the revenues from dispensing services alone, is to expect the impossible. He went on to say that inadequate reimbursement for nondispensing services was forcing pharmacists to spend less and less time in nursing homes, thus depriving patients of even the minimal level of appropriate service.

APhA also disagreed with our position that it was necessary to require separate pharmacists for dispensing and medication review. Although APhA admitted that a potential conflict of interest existed, it believes the best method of preventing a potential conflict from becoming a reality is to adequately compensate pharmacists for nondispensing services.

We doubt that increased compensation alone would remove the financial disincentives for the individual dispensing the drugs to make recommendations to discontinue them.

In its comments on our proposal to separate dispensing and medication review, APhA also said, "Separation of dispensing and nondispensing medication review services will virtually eliminate unit dose drug distribution systems in long-term care facilities." Our proposal is to separate dispensing from the medication review portion of nondispensing services; we made no proposal concerning other aspects of nondispensing services. Unit dose systems 2/ combine dispensing and

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1/"Health Care Delivery System In Nursing Homes," Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, House of Representatives, March 15-16, 1977.

2/In unit dose systems, the pharmacy prepares a tray or other container with each patient's drugs. Each dose is individually packaged and marked; the package is not opened until the dose is to be taken. The pharmacist, rather than the nursing staff, is responsible for checking the drugs against the physician's orders.

nondispensing services with the notable exception of medication review. Only 11 of 68 homes we visited (or about 17 percent) used unit dose systems. APhA suggested that we defer making a recommendation until after completion of experimental projects testing an alternative pharmacy reimbursement system which has a different set of financial incentives. We believe that HEW should issue regulations now and grant such exceptions or waivers as are necessary to accommodate experiments.

We do not agree with HEW's position that separation of the drug dispensing and medication review functions "should be instituted only if there is evidence of actual harm to patients." Our proposal is addressed to a financial disincentive which may contribute to inadequate medication reviews. We do not believe that two barriers to effective medication review--lack of drug information and lack of definition of scope of review--should be addressed while a third--potential conflict of interest--is not addressed.

Therefore, we continue to believe that drug dispensing and medication review should be separated whenever feasible.

CHAPTER 4

CONCLUSIONS, RECOMMENDATIONS, AND HEW, APhA, AND PSRO COMMENTS AND OUR EVALUATION

CONCLUSIONS

Medicaid pays for about half of all nursing home care in the United States. As the major contributor to the cost of Medicaid nursing home patient care, HEW has set up procedures to ensure the quality of that care. With regard to drugs, one way HEW attempts to ensure the high quality of drug therapy is through medication review--a monthly review of each patient's drugs to determine if those drugs are still needed, effective, and safe for that patient.

Drug therapy is a major part of treatment given elderly patients in nursing homes today. Many of these patients concurrently receive several drugs. It is important to closely monitor the drug therapy of these patients because they are more vulnerable to adverse reactions than the general population for a variety of reasons, including the number of drugs they take, the sensitivity of their body systems, and the fact that many of them have multiple ailments.

Based on the results of our samples, we believe that medication review has not been as effective as it should be. Medication review could be more effective if medication reviewers--pharmacists and registered nurses--had ready access to (1) a single source containing authoritative information on drugs commonly used in treating nursing home patients and (2) a clear definition of the scope of these reviews.

FDA-approved drug labeling is the most widely available and widely used source of drug information published either as the package insert or in the Physicians' Desk Reference. Labeling often does not contain enough information about the proper monitoring and use of the drug. As a result, pharmacists and nurses must rely on a variety of other sources of drug information which may or may not be reliable and on their personal drug knowledge, based on their education, training, and experience.

Information included in drug labeling could be improved as a result of the revised labeling regulations issued by

FDA in June 1979. For example, the revised regulations specify that a drug's labeling should include recommendations for tests to be performed, including specific frequencies where appropriate. However, because it will take drug manufacturers several years to revise labeling on all marketed drugs, the extent of improvements will not be known for some time. Also, the revised labeling for each drug probably will not provide medication reviewers with the specific guidelines needed when the drug is used with one or more other drugs in the same therapeutic class or affecting the same body system.

Legislation was introduced in the Congress in 1979 that includes provisions for developing and issuing a drug compendium. If enacted, the development of this document would probably take several years to complete because of the large number of drugs involved.

We believe HEW should immediately disseminate to nursing homes drug utilization guidelines on the more limited number of drugs commonly used in the treatment of nursing home patients. PSROs and other sources have developed criteria on some of these drugs--a knowledge base that can be expanded. PSROs are gradually assuming the States' medical review responsibilities in SNFs, and the States can request PSROs to do so in ICFs as well. Because of their physician involvement, PSROs are a valuable resource in further development of drug-monitoring guidelines, and they have already demonstrated that criteria for proper use and monitoring of drugs can be developed and applied. Furthermore, these criteria could be of immediate use to FDA in its drug labeling improvement program and in developing a drug compendium.

HEW also needs to clearly define the scope of medication review--by both pharmacists and registered nurses. At present, the scope of medication review is left to the interpretation of the individual reviewer. As a result, the scope of review varies considerably among reviewers, and assessing the adequacy of medication reviews is difficult.

In addition to defining the scope of medication review, HEW needs to ensure that training in medication review methodology is available as needed. Some such training was provided under HEW funding in the past, and apparently some efforts are still being made in this regard, although no one knows to what extent.

Finally, we believe that HEW should issue a regulation requiring separation of the medication review component of pharmacist consultant services from drug vendor services whenever feasible. These services were not separated at many of the homes we visited. Although we found no evidence that the pharmacists were not objective in their reviews, we believe separation of these two functions provides for better control in that the pharmacist is not placed in a potential conflict-of-interest situation.

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary direct the Administrator of HCFA to:

--Gather the monitoring and usage criteria that have been developed by PSROs and others for drugs commonly taken by nursing home patients and (1) send the criteria that HCFA judges to have merit to every nursing home participating in the Medicare and/or Medicaid programs, (2) revise and expand the criteria as PSROs and others gain experience in medication reviews and send these revisions to the nursing homes, and (3) share the criteria with FDA for use in its efforts to improve prescription drug labeling.

--Direct the National Professional Standards Review Council to promote continued development of additional drug-monitoring criteria for drugs commonly used in nursing homes, with particular emphasis on drugs and combinations of drugs for which few or no criteria are currently available.

--Incorporate in nursing home regulations a clear definition of the scope of medication review for both pharmacists and registered nurses.

--Issue regulations requiring separation of pharmacist medication review and drug vendor functions whenever feasible.

HEW, APhA, AND PSRO COMMENTS AND OUR EVALUATION

HEW and APhA generally agreed with our first two recommendations regarding the distribution of PSRO screening criteria and

the use of the National Professional Standards Review Council to promote development of additional criteria. HEW is planning to contract for development of sample criteria for long-term care which may include sample drug criteria, and it plans to enlist the support of the National Professional Standards Review Council in promoting drug-monitoring criteria development efforts. HEW stressed that the criteria would be sample criteria to be considered in the development of local criteria. APhA said that any drug criteria disseminated should not be treated as enforceable standards. We do not believe that these reservations are inconsistent with the thrust of our recommendation aimed at involving the clinical expertise of PSROs in improving the quality of patient care in the Nation's nursing homes.

HEW and APhA generally disagreed with our recommendation pertaining to a definition of medication review. Both were opposed to establishing a medication review standard which requires reviewers to follow one system, method, or set of procedures. APhA said the specific terms of our proposal in the draft report were not acceptable because it implied to them that regulations would be issued which would require reviewers to follow one set of procedures rather than allowing the reviewers the option to follow whatever procedures their professional judgment dictated. APhA added that HEW needed to do a better job of apprising nursing homes and health care personnel of the many possible elements of a medication review. HEW also disagreed, stating that the recommendation would require the Government to define through regulation a professional practice. We believe that HEW and APhA misinterpreted our recommendation.

We did not mean to imply that HEW should require that specific methods or systems of medication review be followed. We have therefore revised our recommendation to clarify our position that HEW define the required scope of review--which leaves the reviewer the option of following any method or system which results in the coverage required.

HEW opposed our recommendation requiring a separation of drug dispensing and medication review functions because it believes that regulatory action is needed "only if there is evidence of actual harm to patients" and because it would be difficult for nursing homes to secure a meaningful medication review due to inadequate reimbursment for that function alone. We do not believe that HEW's response pertaining to harm to patients addresses our concerns. Our recommendation is addressed to a financial disincentive which may contribute to

inadequate medication reviews irrespective of whether such reviews result in serious harm to patients. We do not believe that two barriers to effective medication review--lack of drug information and lack of definition of scope of review--should be addressed while a third--potential conflict of interest--is not addressed.

APhA, which in the past has criticized HEW for pharmacist reimbursment policies which encouraged inadequate nondispensing services, disagreed with our recommendation to separate drug dispensing and medication review on the basis that adequate reimbursement for these services represented a more appropriate action to prevent potential conflict of interest from becoming a reality. We doubt that increased compensation alone would remove the financial disincentive for the individual dispensing the drugs to make recommendations to discontinue them. We therefore continue to believe that HEW should require separation of the dispensing and medication review functions whenever feasible.

The Colorado PSRO generally agreed with all our recommendations. It did express reservations about issuing criteria if they were in the form of national standards. The PSRO stressed that criteria are designed only to identify questionable patterns of care and that each case not meeting the criteria must be investigated further. It also pointed out that PSROs could be more effective in medication reviews than either pharmacists or registered nurses because of the opportunity for peer interaction, including intervention to secure constructive action. However, PSRO impact has thus far been limited because some PSROs have not begun review of long-term care, while some of those who have begun this review either have not developed drug criteria or do not have responsibility for reviewing ICF care, which constitutes most nursing home care. Therefore, we believe that pharmacists and nurses will continue to have a major role in medication review for at least the next few years.

SAMPLING METHODOLOGY

Six States were selected for review--California, Georgia, Iowa, Kansas, Massachusetts, and Texas. These States were not randomly selected; they were chosen because they were geographically dispersed and because about 30 percent of the nursing homes in the continental United States were located in them. These States were grouped, or "clustered," for statistical purposes. (See p. 5 for the numbers and distribution of homes and patients.)

The Medicaid patient records we analyzed were randomly selected using a stratified two-stage cluster design. In the first stage, we randomly selected nursing homes, and in the second stage, we randomly selected patients in each of the homes selected in the first stage. During the second stage, we randomly selected two different samples of patients in each home. Some patients were selected in both samples. The two samples were:

--Sample one: the patient universe was all Medicaid nursing home patients taking 1 or more of 23 selected drugs for periods exceeding 6 months.

--Sample two: the patient universe was all Medicaid patients regardless of what drugs they took or for how long.

Our preliminary, or survey, work in this review was done in Kansas and covered only the first random sample of patients for the period January 1976 to October 1977. After completing our visits to the nursing homes in Kansas, we designed the second sample. Consequently, the first sample covers one more State than the second sample. Also, the period covered by both samples in the other States is later--July 1976 to August 1978.

Because the States were not randomly selected, the results for both samples are statistically valid only for the clusters of States covered by the samples. In other words, the numerical results cannot be projected beyond the clusters to the entire country on a statistically valid basis.

In accordance with our stratified two-stage cluster plan, we had randomly picked 20 nursing homes in California. However, after we visited 14 nursing homes, it became apparent

that the results in California would not be substantially different from those in the other States where our visits had been completed. We did not visit the nursing homes in any State in the order in which they were randomly selected; from a statistical viewpoint this is permissible only if all homes are visited, and this was not the case in California. Consequently, we cannot include data from California with clustered data from nursing homes in the other States or in estimates based on the clustered data. These constraints on the use of information from California apply only to the actual patient data from the samples themselves. Other matters, such as expressions of opinion by persons we interviewed in California, are included with the others.

In projecting sample results to the universe of Medicaid nursing home patients, we made appropriate adjustments to assure that the weight given to sample results in each State was proportionate to that State's share of the number of homes in the universe of nursing homes.

There were about 155,000 patients in the five-State cluster and 66,000 of them were eligible for the first sample, while there were about 141,000 patients in the four-State cluster and all of them were eligible for the second sample.

The patients in both samples, however, are generally similar. Three-quarters of the patients in both samples are female. The patients average 80 years of age in the first sample and 79 in the second. Most patients receive intermediate level care--78 and 79 percent, respectively, in the first and second samples. At the time of our review, patients in the first sample had lived in the nursing homes for an average of 46 months, compared to 41 months for the second sample. Patients in the first sample saw their attending physician about once every 59 days, and 90 percent of these visits were in the nursing home. Patients in the second sample saw their attending physician about once every 55 days, and 92 percent of the visits were in the nursing home.

SOURCES OF DRUG-MONITORING CRITERIA USED IN THIS REVIEW

A nursing home patient normally has one or more chronic illnesses and, in many cases, drugs are useful if not essential in treating the illness(es). In the early stages of our review, we identified the top 80 brand-name drugs in terms of total dollars spent for drugs for Kansas Medicaid nursing home patients. Our Chief Medical Advisor examined the labeling for these 80 drugs and identified 23 for which the labeling either clearly said or implied to him that one or more tests were needed to monitor the efficacy or side effects of the drug when the patient was taking the drug for extended periods of time and after the patient's condition and dosage level had become reasonably stable.

The manufacturer-developed and FDA-approved labeling for many of the 23 drugs clearly identified test(s)--laboratory tests (such as blood counts) and other tests (such as electrocardiograms)--that were required to determine if the drug is no longer needed, still needed and having its desired effect, or needed but having an undesired side effect. However, we noted that the labeling did not contain specific guidance on how often each test should be performed, but rather used words, such as "frequent" or "periodically." For example, the "warnings" section of the labeling for Lasix shows the following:

> "Frequent serum electrolyte, CO2, and BUN determinations should be performed during the first few months of therapy and periodically thereafter * * * ." 1/
> (Underscoring added.)

The "precautions" section of the labeling for Diuril and Hydrodiuril states:

> "Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals."
> (Underscoring added.)

1/"CO2" is a carbon dioxide test, and "BUN" is a blood urea nitrogen test.

On September 18, 1978, we submitted to FDA a list of the 23 drugs and our interpretation of those tests needed for each drug. We asked FDA (1) whether, in the opinion of its staff, we had correctly interpreted the labeling regarding the tests needed and (2) what the maximum time interval between the needed tests should be.

In a November 15, 1978, letter, FDA told us that laboratory test recommendations such as "frequent" and "periodically" have no specific meaning. While FDA commented on the tests that were appropriate for each of the 23 drugs, it was unable to recommend specific time intervals for performing the tests. According to FDA's reply, "Except in individual cases, where there are firm data supporting monitoring at given intervals, the frequency of monitoring is properly left to the physician and cannot be specified." FDA officials also suggested that groups of physicians specializing in nursing home practice probably could establish lab test frequency criteria based on their experience in using the drugs.

We used monitoring criteria (1) developed by those PSROs which had begun review and evaluation of long-term care and (2) identified in the medical literature. Twelve PSROs funded by HEW for long-term care evaluation had criteria on file at HEW headquarters. We reviewed this information and found that five of the PSROs had developed criteria on the monitoring or use of selected drugs or types of drugs. The five PSROs were those for Colorado, Utah, Western Massachusetts, Charles River Massachusetts (the suburbs west of Boston), and the Upper Peninsula of Michigan. In our literature search, we found a publication entitled "Drug Utilization Review in Skilled Nursing Facilities: A Manual System for Performing Sample Studies of Drug Utilization." The publication was based on research conducted by the University of Minnesota under a contract with HEW. The five PSROs and the University of Minnesota developed their drug criteria with the advice and assistance of practicing physicians and other health professionals.

The following table shows the 23 drugs included in our review and those for which criteria were available.

Drug	FDA agreed that one or more tests are required to monitor long-term use	Specific frequency of test criteria developed by: At least one PSRO	Specific frequency of test criteria developed by: HEW-funded University of Minnesota study
Aldactazide	Yes	Yes	No
Aldactone	Yes	Yes	No
Aldomet	Yes	No	Yes
Butazolidin	Yes	No	No
Diabinese	No	No	No
Diuril	Yes	Yes	No
Dyazide	Yes	Yes	No
Hiprex	Yes	No	No
Hydrodiuril	Yes	Yes	Yes
Inderal	No	No	No
Kaon	Yes	No	No
K-Lyte	Yes	No	No
Lanoxin	(a)	Yes	Yes
Lasix	Yes	Yes	No
Librax	Yes	No	No
Macrodantin	Yes	No	No
Ritalin	No	No	No
Septra	Yes	No	No
Ser-Ap-Es	Yes	No	No
Sinemet	Yes	No	No
Slow-K	Yes	No	No
Theragran	Yes	Yes	No
Trinsicon	Yes	Yes	No

a/With regard to monitoring Lanoxin, FDA stated that "* * * use of Lanoxin does not require general monitoring although assessment of electrolytes, kidney function, and ECG [electrocardiogram] are called for in various specific circumstances. For example, potassium measurements would be essential in patients treated with diuretics."

On the basis of FDA's comments, we eliminated three of the above drugs from our review--Diabinese, Inderal, and Ritalin. We eliminated another drug--Butazolidin--from our review because only one patient in our sample took the drug for at least 6 months, which was the minimum length of time a patient had to take a drug to be included in this sample.

CRITERIA USED

One or more PSROs and/or the University of Minnesota made specific test and test frequency recommendations for 10 drugs--Aldactazide, Aldactone, Aldomet, Diuril, Dyazide, Hydrodiuril, Lanoxin, Lasix, Theragran, and Trinsicon. We determined whether patients taking the 10 drugs met the frequency of test recommendations. Our findings regarding these 10 drugs are shown in appendixes III and IV. For those nine drugs for which FDA recommended tests but the experts did not recommend specific frequency of test, we determined the length of time patients took the drugs without receiving the FDA-recommended tests. Our findings regarding these nine drugs are shown in appendix V.

On some of the 10 drugs for which testing frequency criteria had been developed, the experts differed as to tests to be performed or the frequency with which the tests should be performed. In performing our analysis, we used the most lenient criteria. For example, we used the longest interval between tests as our minimum standard where sources differed as to frequency of a test. Some PSROs also established monitoring procedures other than tests for drugs included in our review. These monitoring procedures are discussed below where applicable. The following is a discussion of criteria established by each source.

Criteria used by GAO for diuretics:

Any electrolytes test at least once every 12 months.

Diuretics are used to treat edema (an excessive accumulation of fluids in the body's tissues). Diuretics cause reduction of fluids in the tissues by increasing the excretion of fluids. A problem with diuretics is that blood serum electrolytes are excreted with the fluids, and this may cause blood electrolyte imbalance, which can adversely affect the functioning of the heart. Potassium is the electrolyte most likely to be affected by diuretics, and severe potassium

imbalance (either too much or too little) can cause irregularities in the heartbeat, which can sometimes be fatal. Potassium loss can be dealt with by (1) using a potassium-sparing diuretic or (2) offsetting the loss with extra potassium either in the diet or by taking potassium-supplementing medications.

Six diuretics were included in our review. The labeling for three--Aldactazide, Aldactone, and Dyazide--states that they are potassium sparing. The labeling for the other three diuretics--Diuril, Hydrodiuril, and Lasix--indicates they are potassium depleting.

All five PSROs that developed specific drug-monitoring criteria recommended that periodic electrolytes tests (potassium, sodium, calcium, and chlorides) be performed on patients taking a diuretic. The PSROs' recommendations varied. One PSRO specified an electrolytes test every 6 months, and two specified electrolytes tests every 12 months. Another recommended electrolytes tests (potassium as a minimum) every 6 months, but only if a potassium-depleting diuretic was used. The remaining PSRO tied its recommendations to the patient's diagnosis and the type of drug as follows:

--For patients with hypertension, a potassium test every 1 to 3 months.

--For patients with congestive heart failure, a potassium test every 6 months.

Two PSROs also specified that the patient's blood pressure and weight be taken weekly. The recommendation for Hydrodiuril in the University of Minnesota study was potassium tests every 3 months; sodium, calcium, and chloride tests every 6 months; and weekly recordings of weight, pulse, and blood pressure.

Criteria used by GAO for cardiac stimulants:

Either (1) any electrolytes test as well as a kidney function test and an electrocardiogram at least every 6 months or (2) a serum digitalis test at least once every 12 months.

Digoxin, the cardiac stimulant included in our review, affects the electrical conduction system of the heart. Digoxin, which is a digitalis preparation sold under the brand name Lanoxin, tends to increase the muscular contraction of the heart, thus helping patients with congestive heart failure by increasing the heart's output of blood. The drug also delays the transmission of electrical impulses through the conduction system of the heart to restore normal heart rate and rhythm.

Digoxin has a narrow margin of safe use because it tends to accumulate in the blood and may reach toxic levels. The more serious consequences of digitalis intoxication are arrhythmia (irregularity of heart rhythm) and heart blockage. Digitalis intoxication can also occur at otherwise tolerated dosage levels when the blood serum potassium level is below normal, indicating a need to closely monitor the patient's potassium level as well.

Three PSROs had established specific testing recommendations. Two PSROs specified annual serum digitalis level tests. The third specified that patients with congestive heart failure taking digoxin should receive the digitalis level test but did not specify a frequency.

Another PSRO stated that "appropriate monitoring of this drug is crucial" but had not been able to develop a consensus about specific tests and frequencies. The University of Minnesota recommended the following tests: potassium test every 3 months; sodium, chloride, and calcium tests every 6 months; an electrocardiogram every 6 months; and a kidney function test every 6 months.

APPENDIX II

Criteria used by GAO for hematinics:

> At least every 6 months any one of (1) a hemoglobin test, (2) a complete blood count, or (3) a red blood count.

Hematinics are drugs used to treat certain types of anemia. Hematinics increase the amount of iron containing pigments in the blood cells. Hematinics should be monitored to determine whether the anemic condition is improving by use of hematinic therapy. Two hematinics were included in our review--Theragran (hematinic version) and Trinsicon.

Only one of our six criteria sources--a PSRO--had developed criteria on hematinics. The PSRO specified that at least every 6 months the patients receive a hemoglobin test, a red blood count, or a complete blood count.

Criteria used by GAO for antihypertensives:

> A kidney function test at least every 6 months and an electrocardiogram at least every 12 months.

The antihypertensive drug included in our review--Aldomet--acts to relax constricted blood vessel walls and thus lower blood pressure. Two of the five PSROs recommended that patients taking antihypertensive drugs have their blood pressure taken daily or weekly. The University of Minnesota study recommends that recipients of Aldomet be given a kidney function test at least every 6 months and an electrocardiogram at least every 12 months.

EXPLANATORY NOTE

The table on pages 70 and 71 shows the drugs, the tests recommended to monitor the drugs, the test frequency we selected as discussed in appendix II, the raw numbers of Medicaid patients whose records we reviewed in the five-State cluster and in California, and our estimates of the numbers of Medicaid nursing home patients in the five-State cluster who took the drugs and the percentages of those patients who were not tested as often as recommended. The sum of the raw numbers of patients taking different drugs within a drug class exceeds the total number of patients taking drugs in that class because some patients took more than one drug in a class.

The "plus-minus" figures following the estimates are the sampling errors, which reflect the uncertainty inherent in estimating. For example, we believe the actual number of Medicaid patients in the five-State cluster taking diuretics is somewhere between 37,904 (33,905 plus 3,999) and 29,906 (33,905 minus 3,999). Similarly, we believe that somewhere between 71 and 51 percent of the actual number of Medicaid patients in the five-State cluster did not receive with the recommended frequency those tests needed to monitor the diuretics they were taking. Also shown in the table is the 1978 rank for the 10 drugs. Rank is based on the volume of new and refill prescriptions filled in retail pharmacies during 1978. Eight of the 10 drugs are ranked in the top 200, and 5 of them are in the top 15. The ranks are shown to illustrate the point that we are dealing with drugs that are commonly prescribed for large numbers of Americans.

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tables can appear

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APPENDIX III

RESULTS OF GAO ANALYSIS OF RECOMMENDED TESTING PERFORMED ON MEDICAID PATIENTS RECEIVING TEN SELECTED DRUGS

Drug	1978 Rank [a]	Type of Test	Test Frequency	Number of Medicaid patients in 53 homes Reviewed	Not receiving tests with specified frequency Number	Percent
DIURETICS						
Potassium sparing						
Aldactizide	52	Electrolytes	12 months	23	10	43
Aldactone	147	Electrolytes	12 months	5	1	20
Dyazide	6	Electrolytes	12 months	32	17	53
Potassium sparing sub-group				58	26	45
Potassium depleting						
Diuril	56	Electrolytes	12 months	22	13	59
Hydrodiuril	15	Electrolytes	12 months	30	18	60
Lasix	4	Electrolytes	12 months	138	90	65
Potassium depleting sub-group				188	119	63
Diuretics class				238	141	59
CARDIAC STIMULANTS						
Lanoxin	11	Criteria category I (3 tests)				
		Kidney function	6 months	187	172	92
		Electro-cardiogram	6 months	187	186	99
		Electrolytes	6 months	187	159	86
		all 3 tests		187	187	100
		Criteria category II (1 test)				
		Digitalis level	12 months	187	169	90
		(Criteria categories I and II combined)		187	169	90
HEMATINICS						
Theragran (hematinic)	N/R	Hemoglobin or red blood count or complete blood count	6 months	10	7	70
Trinsicon	N/R	Hemoglobin or red blood count or complete blood count	6 months	15	14	93
Hematinics class				25	21	84
ANTI-HYPERTENSIVES				26		
Aldomet	10	Kidney function	6 months		24	92
		Electro-cardiogram	12 months		25	96
		Both tests			26	100
OVERALL: Ten Drugs				349	287	82

Based on volume of new and refill perscriptions filled in retail pharmacies during 1978. Source: *Pharmacy Times*, "Top 200 Drug Survey," April 1979. (N/R indicates drug not ranked in top 200.)

APPENDIX III

RESULTS OF GAO ANALYSIS OF RECOMMENDED TESTING PERFORMED ON MEDICAID PATIENTS RECEIVING TEN SELECTED DRUGS

FIVE STATE CLUSTER		CALIFORNIA		
Projected number of Medicaid patients in 5 States		Number of Medicaid patients in 14 homes		
	Not receiving tests with specified frequency		*Not receiving tests with specified frequency*	
Taking drugs (sampling error)	Percentage (sampling error)[b/]	Reviewed	Number	Percent
2579(±1700)	41(±20)	4	1	25
578(±562)	29(±28)	5	3	60
4415(±2360)	53(±10)	20	14	70
7484(±2975)	51(±18)	28	18	64
2218(±1584)	63(±26)	3	1	33
2637(±1499)	54(±19)	7	3	43
21062(±4303)	65(±9)	40	14	35
26155(±4134)	64(±10)	50	18	36
33905(±3999)	61(±10)	73	33	45
	86(±9)	52	50	96
	99(±2)[c/]	52	52	100
	86(±8)	52	44	85
	100(±0)	52	52	100
	86(±8)	52	47	90
24852(±2864)	86(±8)	52	47	90
1627(±1186)	39(±24)	3	2	67
1352(±664)	66(±27)	1	1	100
2980(±1321)	67(±16)	4	3	75
3154(±1297)	63(±21)	9	9	100
	78(±9)		9	100
	100(±0)		9	100
48645(±2923)	81(±7)	97	75	77

[b/] The sampling errors are at the 95 percent confidence interval.

[c/] The percentages shown are "rounded" to the nearest whole number. The actual percentages cannot, of course, exceed 100 percent.

APPENDIX IV

NUMBER OF MONTHS MEDICAID PATIENTS RECEIVED SELECTED DRUGS WITHOUT RECEIVING RECOMMENDED TESTS: TEN DRUGS WITH TESTING FREQUENCY CRITERIA

FIVE STATE CLUSTER

Drug	Type of Test	Test Frequency	Patients Reviewed	Number tested within timeframes	Tested—but not within timeframes (months on drug without tests) 7–12	13–18	19–24	Over 24	Not tested during review period [a] (months on drug without tests) 7–12	13–18	19–24	Over 24
Diuretics												
Aldactazide	Electrolytes	12 months	23	13	N/A	2	0	0	N/A	1	4	3
Aldactone	Electrolytes	12 months	5	4	N/A	1	0	0	N/A	0	0	0
Dyazide	Electrolytes	12 months	32	15	N/A	5	0	0	N/A	4	5	3
Diuril	Electrolytes	12 months	22	9	N/A	1	1	0	N/A	4	1	6
Hydrodiuril	Electrolytes	12 months	30	12	N/A	8	1	0	N/A	3	6	0
Lasix	Electrolytes	12 months	138	48	N/A	25	10	1	N/A	18	21	15
Cardiac Stimulants												
Lanoxin	Kidney function	6 months	187	15	36	39	14	1	0	20	33	29
	Electro-cardiogram	6 months	187	2	31	26	12	1	1	29	42	43
	Electrolytes	6 months	187	28	41	36	10	0	1	18	25	28
	Digitalis level	12 months	187	18	N/A	24	13	0	N/A	34	49	49
Hematinics												
Theragran	Hemoglobin or red blood count or complete blood count	6 months	10	3	2	2	1	0	1	1	0	0
Trinsicon	Hemoglobin or red blood count or complete blood count	6 months	15	1	4	3	0	0	3	1	1	2
Anti-hypertensives												
Aldomet	Electro-cardiogram	12 months	26	2	N/A	5	1	0	N/A	9	5	4
	Kidney function	6 months	26	2	6	7	2	0	0	4	3	2

[a] Patients in this group did not receive the test during our review period and the interval shown represents the time the patient took the drug during our review period until (1) the drug was discontinued, (2) the patient left the home (includes deaths), or (3) the ending date of our review period.

APPENDIX V

NUMBER OF MONTHS MEDICAID PATIENTS RECEIVED SELECTED DRUGS WITHOUT RECEIVING RECOMMENDED TESTS: NINE DRUGS WITH NO TESTING FREQUENCY CRITERIA[a]

FIVE STATE CLUSTER

Drug	Type of Test	Patients reviewed	Tested during review period (months on drug without tests)					Not tested during review period[b] (months on drug without tests)				
			1--6	7--12	13--18	19--24	Over 24	1--6	7--12	13--18	19--24	Over 24
Anti-hypertensives												
Ser-Ap-Es	Complete blood count	22	2	6	5	3	0	1	1	2	0	2
	Lupus erythematosus cell	22	0	0	0	0	0	2	5	3	8	4
	Electrolytes	22	6	3	4	0	0	1	1	3	1	3
	Blood urea nitrogen	22	3	3	6	1	0	1	2	3	1	2
Anti-Parkinson's												
Sinemet	Complete blood count	17	2	1	5	1	0	0	0	3	2	3
	Kidney function	17	1	1	3	1	0	1	0	5	2	3
	Liver function	17	1	1	2	0	0	1	0	6	2	4
	Electro-cardiogram	17	0	1	2	0	0	1	1	5	2	5
Anti-spasmodic												
Librax	Complete blood count	7	1	3	1	0	0	0	0	1	1	0
	Liver function	7	2	0	1	0	0	0	0	2	2	0
Anti-bacterials												
Hiprex	Kidney function	9	0	0	0	0	0	0	2	4	3	0
	Liver function	9	0	0	1	1	0	0	3	2	2	0
Macrodantin	Kidney fuction	7	0	4	0	0	0	0	2	0	1	0
Septra	Complete blood count	6	2	0	2	0	0	0	1	0	1	0
Potassium supplements												
Kaon	Serum potassium	33	7	8	6	1	0	0	1	3	6	1
K-Lyte	Serum potassium	11	4	2	0	0	0	0	2	1	1	1
Slow K	Serum potassium	33	9	5	5	1	0	0	4	2	5	2

[a] The tests shown were identified by the Food and Drug Administration (FDA) as desirable to periodically monitor the drugs. FDA was unable to suggest specific time intervals for performing the tests.

[b] Patients in this group did not receive the test during our review period and the interval shown represents the time the patient took the drug during our review period until (1) the drug was discontinued, (2) the patient left the home (includes deaths) or (3) the ending date of our review period.

APPENDIX VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

REFER TO:

OFFICE OF THE INSPECTOR GENERAL

APR 2 1980

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "The Department Of Health, Education, And Welfare Should Do Significantly More To Assure Proper Drug Treatment Of Medicaid Nursing Home Patients." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard B. Lowe III
Acting Inspector General

Enclosure

GAO Note: Page references in this appendix may not correspond to page numbers in the final report.

APPENDIX VI

Comments of the Department of Health, Education, and Welfare on the General Accounting Office's Draft Report Entitled, "The Department of Health, Education, and Welfare Should Do Significantly More To Assure Proper Drug Treatment of Medicaid Nursing Home Patients"

Overview

The report suggests that drug labeling is inadequate because it either does not contain specific information on how the drug should be monitored or it does not describe the implications of using multiple drugs affecting the same body system (for example, pages i and ii of the Digest, pages 10-13 of the text). We do not believe these are labeling inadequacies, but rather that determinations about the frequency, extent, and nature of patient monitoring must be made by the appropriate health professional on a case-by-case basis taking into consideration all relevant factors such as the patient's general condition, concomitant treatment, etc. We support periodic tests but not mandatory testing at specifically prescribed intervals because of these variable patient factors and the potential increase of costs would not prove to be beneficial to the patients. Also, treatment using concomitant drug therapy may be appropriate for some patients and inappropriate for others. This is a decision that can only appropriately be made in the context of specific situations dealing with individuals rather than through generalizations in drug labeling.

Furthermore, the report does not recognize the myriad combinations and permutations that are possible with the number of drugs that are presently available and the impossibility of addressing each and every one of these in drug labeling or in a drug compendium (reference page 44). In situations where the Food and Drug Administration (FDA) has reason to believe that certain drugs may be used in combination or that certain drugs, when used in combination, will produce adverse effects, the agency requires appropriate warnings in the labeling. This is not possible for the majority of drugs, however, because of the immense expenditure of resources that would be required to determine the effects produced by all the possible drug interactions and to develop specific labeling. Nor is it possible or practical for a drug compendium to contain information on the infinite number of possible permutations and combinations of drug entities that could result from multiple drug therapy. Furthermore, many standard texts on pharmacology, toxicology, and therapeutics contain information concerning drug interactions.

The General Accounting Office (GAO) suggests that the Department of Health, Education, and Welfare (HEW) should move toward the development of a single source of information. It is unrealistic, and possibly undesirable, to expect that all information about drugs will ever be contained in one source. Drug labeling is intended to be used in the context of medically well informed professionals exercising judgment concerning individual patients who have unique health conditions and drug responses. We believe the majority of approved drug labeling is adequate in this context. Approved labeling has been subjected to the rigorous requirements of the new drug approval process. In order to be approved for marketing, a drug must be shown to be safe and effective in controlled clinical trials for the conditions

for use for which the manufacturer intends to promote the drug and which are expressed in its approved labeling. In addition to indications of use, FDA regulations require the labeling to contain information of contraindications to its use, warnings, precautions, adverse reactions, potential effects in pregnancy (treatology potential), and dosage and administration. Approved labeling, therefore, is an authoritative statement of those uses for which the drug's effectiveness has been demonstrated in accordance with a rigorous statutory standard.

Also, the identification of suspected problems through application of criteria is just a first step. More intense review is needed to determine whether the exception is warranted. Thus, the criteria alone would not improve drug utilization without the implementation of a process to apply these criteria by skilled professionals. We note that GAO apparently identified exceptions to selected criteria without examining each patient's situation to determine if there were valid reasons for the exception.

GAO Recommendation

We recommend that the Secretary of Health, Education, and Welfare direct the Administrator, Health Care Financing Administration to:

-- gather the monitoring and usage criteria for drugs commonly taken by nursing home patients that has been developed by PSROs and others and (1) send the criteria that is judged to have merit to every nursing home participating in the Medicare and/or Medicaid programs, (2) revise and expand the criteria as PSROs and others gain experience in medication reviews and send these revisions to the nursing homes, and (3) share the criteria with FDA for use in its efforts to improve prescription drug labeling;

Department Comment

We concur in part.

Distributing criteria has merit if they are considered useful by the reviewers and accepted by the physician. However, in the PSROs' experience, specific criteria developed by physician groups in one part of the country are not always deemed appropriate by physician groups in other parts of the country. The concept of sample criteria to be considered in the development of local criteria is more acceptable. HEW is in the process of contracting for development of sample criteria for long-term care generally and we expect that contract to result in the development of sample drug criteria. It should be noted that the criteria which was developed by the University of Minnesota through a contract with HEW have been made available to nursing homes since 1975. GAO notes that 4,000 copies of this document have been printed. Most of these have been made available to pharmacists and nurses who work in nursing homes.

Currently, FDA has two major efforts underway to improve prescription drug labeling. The first is issuance of a new regulation which will require a standardized format for physician labeling of prescription drugs and provide standards for the kind of information that must appear in each section of the required format.

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Drug labeling is intended to advise health care professionals about potential hazards in the use of a drug and convey documented statements about its safety and effectiveness. The uniform format includes sections on dosage and administration; precautions; warnings; and adverse reactions as well as other information.

The second major labeling effort is targeted at those drugs which were "grandfathered" under the FDA. "Grandfathered" drugs are those which were exempted from the requirements of the Federal Food, Drug, and Cosmetic Act on the basis of having been marketed prior to 1938. These drugs have not undergone the rigorous drug approval process and subsequent review of claims, indications, and warnings which appear on labels. The class labeling project will provide modern labeling for these products and will thereby help to correct some known problems in providing better and more complete drug information.

GAO Recommendation

— direct the National Professional Standards Review Council to promote continued development of additional drug monitoring criteria for drugs commonly used in the nursing home setting, with particular emphasis on drugs and combinations of drugs for which little or no criteria is currently available;

Department Comment

At a future meeting of the Council, we will brief them on this GAO report and enlist their support in promoting drug monitoring criteria development efforts.

GAO Recommendation

— incorporate in the nursing home regulations minimum standards for medication review for both pharmacists and registered nurses, and include in those standards a definition of the scope of review required of pharmacists and registered nurses; and

Department Comment

We do not concur insofar as this recommendation suggests that a required system or method of medication review be mandated in regulation. This is objectionable because it requires the Government to define through regulations a professional practice.

The proposed revision to the conditions of participation for Skilled Nursing Facilities and Intermediate Care Facilities currently being prepared for publication will include "limit standards" which are intended to reduce the amount of unaccounted for schedule drugs, drug wastage, and errors in administration within the facility. The 5 percent drug administration error rate being proposed is a tentative figure and is based on a specific definition of drug administration error which we have developed according to expert opinion and studies conducted in hospitals and long-term care facilities.

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In addition, the American Pharmaceutical Association has already, through a contract with HEW, developed standards for medication review (see page 59 of the GAO report). These standards have been made widely available as the GAO report states, and any pharmacist who wants them can obtain them.

GAO Recommendation

— issue regulations requiring separation of pharmacist medication review and drug vendor functions wherever possible.

Department Comment

We do not concur.

We share GAO's concern of a potential conflict of interest, but believe that regulations should be instituted only if there is evidence of actual harm to patients. We take some relief in the fact that GAO's findings did not reflect any evidence of actual adverse effects on patients. It should also be noted that separation would, because of inadequate reimbursement for drug regimen reviews, seriously limit the ability of facilities to secure any meaningful review of records. Currently, reimbursement for dispensing services are supporting, to a large degree, the drug regimen review activity.

AMERICAN PHARMACEUTICAL ASSOCIATION
The National Professional Society of Pharmacists

March 6, 1980

Mr. Gregory J. Ahart, Director
Human Resources Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

This responds to your letter of February 6, 1980, addressed to Dr. Richard P. Penna, inviting American Pharmaceutical Association (APhA) comments on a draft of the GAO Proposed Report to Congress entitled "The Department of Health, Education, and Welfare Should Do Significantly More to Assure Proper Drug Treatment of Medicaid Nursing Home Patients."

APhA is the national professional society of pharmacists. It includes among its 55,000 members pharmacists who practice in many environments--including nursing homes--and also students, educators, and scientists. Pharmacists contribute significantly to the quality of care being provided to patients in long-term care facilities by monitoring drug therapy of these patients, and we are gratified that the draft report is strongly supportive of that role. The draft report contains two specific recommendations with which APhA agrees and two with which we take issue.

APhA agrees with the draft report's basic thrust that health professionals need more drug information on drug products, especially information related to the use of drug products in elderly patients. It is APhA's view that: (1) GAO should encourage HEW and other agencies (private and public) to develop and distribute drug information specifically designed to assist practitioners in caring for elderly patients; (2) PSROs should be encouraged to develop criteria for drug use in long-term care facilities; (3) HEW, to the extent that it has criteria developed by five PSRO pilot projects, should be encouraged to distribute this information to all PSROs; (4) requiring state Medicaid agencies to assess the quality of pharmacists' and nurses' review of drug therapies is impractical and unworkable; and (5) requiring the separation of medication review and drug dispensing functions is not practical and is inconsistent with current trends toward utilizing unit dose drug distribution systems in long-term facilities.

There follow APhA's particularized comments on each specific GAO recommendation to the Secretary of Health, Education, and Welfare.

2215 CONSTITUTION AVENUE, N.W., WASHINGTON, D.C. 20037 • (202) 628-4410
CABLE ADDRESS: AMPHARMA

RECOMMENDATION I

--Gather the monitoring and usage criteria for drugs commonly taken by nursing home patients that has been developed by PSROs and others and (1) send the criteria that is judged to have merit to every nursing home participating in the Medicare and/or Medicaid programs, (2) revise and expand the criteria as PSROs and others gain experience in medication reviews and send these revisions to the nursing homes, and (3) share the criteria with FDA for use in its efforts to improve prescription drug labeling.

APhA supports this recommendation because we believe that information regarding PSRO drug use criteria is of potential beneficial use in assisting long-term care facilities and health care personnel to maximize patient care. We hasten to point out, however, that when disseminated these criteria are valuable as educational, not regulatory, tools.

Criteria developed by PSROs are screens that are utilized only to identify unusual practice patterns of professionals for further inquiry. Criteria are not enforceable standards, as the draft report seems to imply. Indeed, among the five PSROs studied in the draft report, the criteria for laboratory tests, which the GAO staff considered, varied markedly. That is to be expected since each PSRO is mandated to develop criteria which it believes contribute to quality care in its region. The reason why PSRO criteria are used only as review screens is that there are often valid reasons why criteria were not met in specific instances. These reasons are frequently attributable to individual patient variations and treatment environments which cannot be predicted in developing criteria and must be considered only on the basis of individual treatment assessment.

Consequently, the conclusion suggested in one instance by the draft report that the care provided to patients, for whom five drugs are prescribed, is of poor quality because certain laboratory testswere not performed, simply is not justified. The PSROs themselves would not reach such a conclusion even though these cases might be screened out for further study. There exists no magic formula by which patient care, particularly among the elderly, can be evaluated universally. One patient may tolerate a battery of tests while another may not, necessitating alternative monitoring procedures.

For example, patients receiving "cardiac stimulants" can be monitored by reviewing their pulse on a daily basis. Patients

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receiving diuretics are often prescribed diets or drug products rich in potassium and, as a result, many physicians feel that further testing is unnecessary and not cost-effective. In view of the fact that hematinics are nontoxic and inexpensive, physicians feel that the cost involved in running blood studies on patients receiving hematinics is not justified by the data that would be derived from such studies.

APhA would therefore oppose any recommendation to adopt national criteria for drug use applicable to long-term care facilities. Such an action on the part of HEW would be contrary to the intent of Congress in establishing Professional Standards Review Organizations. The fact that the five PSROs cited in the draft report, in considering local needs and conditions, developed drug use criteria which vary substantially is evidence that it would be extremely difficult from a practical point of view, and probably detrimental from a health care standpoint, to develop national drug use criteria.

APhA agrees fully with the draft report's conclusion that health professionals serving elderly patients could benefit by more complete and accurate drug information than is currently available. We have supported the concept of a national compendium of drug information for several years. APhA is deeply concerned that HEW has thus far failed to produce or support the production of this information resource. APhA believes that GAO can contribute significantly to quality patient care by pressing the Department to expedite its development of such a compendium while at the same time encouraging more PSROs to develop drug use criteria for long-term care facilities.

RECOMMENDATION II

--Direct the National Professional Standards Review Council to promote continued development of additional drug monitoring criteria for drugs commonly used in the nursing home setting, with particular emphasis on drugs and combinations of drugs for which little or no criteria is currently available.

As suggested by the prior comments, APhA agrees with this recommendation.

RECOMMENDATION III

--Incorporate in the nursing home regulations minimum standards for medication review for both pharmacists and registered nurses, and include in those standards a definition of the scope of review required of pharmacists and registered nurses.

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Regrettably, APhA must oppose the specific terms of this recommendation, because we do not believe that the regulatory approach it would mandate is the correct one to remedy the deficiency identified in the draft report. Nonetheless, while disagreeing with the approach taken, APhA does agree with the thrust of the draft report--that HEW should do more to apprise long-term care facilities and health care personnel of the many possible (not required) elements of a medication review which are available to assist in optimizing patient care. Thus, it is not a question of "minimum" medication review standards which must be performed in "lock-step" at risk of being in violation of federal requirements. Rather, HEW should focus attention on medication review so as to balance the potential process benefit against patient care needs. In this sense, the frequent use in the draft report of the term "guidelines" is appropriate, since it is guidance that is needed, not threats.

The authors of the draft report decry the fact that "we were unable to draw any conclusions as to the adequacy of these reviews because HEW has not established minimum standards for them." APhA will strongly oppose any effort to reduce pharmacists' medication reviews or their evaluation to a rote procedure with passing grades dependent only on the number of blanks filled in on a check sheet. Room must be left for the exercise of professional judgment.

In several places the draft report complains that, because there are no definitive guidelines for medication review, pharmacists and nurses are "left to develop their own interpretation." The development of the ability to exercise such judgments is precisely why government has supported health professions education over the years. The apparent view of the draft report that professional judgment must be subordinate to administrative facility is inconsistent with policies established by other federal agencies and departments. It is also contrary to the policy established by the United States Congress in requiring, among other things, that schools of pharmacy include courses in clinical (patient care oriented) pharmacy in their curricula in order to receive federal capitation support.

While the draft criticizes a lack of uniformity in medication review procedures, it should be expected that review procedures among pharmacists serving long-term care facilities would differ. Such procedures should be established based on the varying needs and characteristics of each facility, which include the number of patients, types of illnesses, age of patients, and location of facility. The draft report states "we found that the scope of reviews by some pharmacists was less comprehensive than that recommended by APhA" and "while

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the descriptions of review procedures followed by pharmacists we interviewed generally agreed with the scope of medication review recommended by the APhA, some pharmacists were deviating in important aspects". The authors clearly have misunderstood the nature and intent of the APhA project. Its purpose was to orient pharmacists and others to the medication review process. The set of procedures outlined by APhA is neither standardized nor required in all instances. It is one set of procedures; there can be many others.

The draft report recognizes that current HEW regulations requiring state agencies to review long-term care facilities do not require the inspection teams to assess the medication reviews performed by pharmacists. There is little likelihood that state reviewers could ever be trained adequately to assess the appropriateness or quality of pharmacist reviews unless they are capable of understanding the reasons for doing or not doing something in evaluating those pharmacist reviews. APhA has supported the development of "indicators" which would assist state surveyors in determining whether pharmacists performed certain functions and which would help indicate whether required medication reviews were taking place (e.g., noting that the physician had been called regarding duplicate medications). These indicators are not an assessment of the pharmacist reviews, but evidence that the review has taken place. The quality of the review must be left to the decision of the facility administrator, pharmacist, medical director, and ultimately, the PSRO in that area.

RECOMMENDATION IV

--Issue regulations requiring separation of pharmacist medication review and drug vendor functions wherever possible.

The background suggests that there is a potential conflict of interest when the same pharmacist who provides medication to a facility reviews drug therapy in that facility. The draft report indicates quite clearly, however, that the GAO study revealed no evidence that the pharmacists observed were not objective in their review. Some potential for conflict of interest obviously exists among providers in health care delivery. For example, physicians could treat non-existant diseases or require patients to return for unnecessary follow-up visits. Hospitals might charge for nonessential services. The fact that GAO found no evidence of pharmacist abuse is significant, and any potential for conflict of interest must be balanced against other factors.

Separation of dispensing and nondispensing medication review services will virtually eliminate unit dose drug distribution systems in long-term care facilities. For such systems to be utilized with optimum efficiency and economy, the pharmacist providing the drug products and the nondispensing pharmaceutical services must be the same person. In a report published November 20, 1972 entitled "Study of Health Facilities' Construction Costs," the GAO discussed the positive advantages that a unit dose drug distribution system could contribute to hospitals. The report discusses the problems associated with conventional drug distribution systems, including medication errors, staff inefficiency, and medication loss. It states "Our study of technological advancements in medication distribution systems showed that an alternative distribution, referred to as the unit dose system, has the potential to overcome some of the deficiencies of conventional systems." Later the report says "Our comparative analysis of the life cycle costs for conventional and unit dose distribution systems showed that unit dose distribution systems have lower life cycle costs than conventional distribution systems at higher annual prescription ranges. The life cycle savings are largely attributed to a reduction in nursing time for administering medications." A number of long term care facilities currently use unit dose distribution systems and report low rates of medication errors and more efficient use of pharmacists' and nursing time.

[See GAO note.] The GAO has, therefore, recognized that a major benefit of the unit dose system is its efficiency in conserving nurses' and pharmacists' time. Requiring different dispensers and medication reviewers would introduce substantial inefficiencies into the unit dose system. In a unit dose program, pharmacists review patients' drug therapy on a daily basis every time they dispense patients' medication orders. Experience reveals that many drug interactions and duplications are detected at this time. As a result, the time spent reviewing this aspect of therapy on a daily basis does not have to be repeated during the monthly medication review, and the reviewer's attention can be focused on other areas such as stop orders, drug administration errors, or recommending laboratory tests. Moreover, pharmacists who use unit dose systems are, by virtue of their daily contact with the patients' total drug regimen, extremely familiar with the therapies of all patients they serve. This fact contributes substantially to the efficiency, completeness, and adequacy of the monthly medication review.

The sole apparent basis for potential conflict of interest is that most pharmacists who provide drug products to nursing homes currently are reimbursed on a fee-for-service, or fee-per-drug-product-dispensed basis. However, capitation

GAO note: This statement is not correct. The 1972 GAO report cited above did not attribute to the unit dose system savings in pharmacists' time.

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methods for compensating pharmacists who provide drug products and nondispensing service are now being tested. In these systems, pharmacists are reimbursed a fixed dollar amount for a stated period of time to cover all drug products dispensed as well as nondispensing services. A capitation system provides a financial incentive for pharmacists to decrease drug utilization in long-term care facilities. Currently, Iowa is studying a capitation system for Medicaid out-patients and California is studying a similar system for nursing home Medicaid patients. Mandating the separation of dispensing and review functions would adversely affect these studies and other efforts to encourage capitation plans. GAO would be well advised to await the outcome of these experimental projects before making the separation recommendation.

Until recently, HEW policy discouraged states from compensating a pharmacist who provides nondispensing service (consulting service) when that same pharmacist also provides drug products for Medicare and Medicaid patients. The HEW view was that such pharmacists receive a sufficient income from the dispensed prescription drug products and, consequently, that nondispensing service should be provided at no charge. This shortsighted policy was responsible for many state Medicaid agencies failing to recognize nondispensing pharmaceutical service as reimbursable even through other parts of the Medicare/Medicaid conditions for participation clearly indicated that it was such. While this HEW policy has largely been eliminated, much of its effect remains and pharmacists in many states still experience difficulty in receiving Medicaid compensation for providing nondispensing service. The best method to prevent a potential conflict of interest from becoming a reality is to assure that pharmacists who provide nondispensing service are adequately compensated for that service apart from the dispensing of drug products. An affirmative HEW policy to this end would go far in counterbalancing the conflict of interest potential discussed in the draft report.

CONCLUSION

APhA is pleased to have had the opportunity to consult with GAO staff during the progress of the study, and appreciates the opportunity to review and comment on the draft report. The Association hopes that its comments will be useful to the GAO in finalizing its report in a manner that is consistent with logic and sound principles of drug therapy. APhA staff would be most pleased to work with GAO staff in further developing the Association's recommendations.

Sincerely,

William S. Apple, Ph.D.
President

WSA:klm

APPENDIX VIII

COLORADO FOUNDATION FOR MEDICAL CARE
1601 East 19th Avenue
Denver Colorado 80218
Phone (303) 861-1221

February 20, 1980

Gregory J. Ahart
Director
Human Resources Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Colorado Foundation for Medical Care asked me to comment upon your draft report, "The Department of Health, Education, and Welfare Should Do Significantly More to Assure Proper Drug Treatment of Medicaid Nursing Home Patients".

My observations stem from experience as a practicing internist and close involvement with the entire Colorado PSRO effort. I am an Associate Medical Director for both hospital review and long term care review programs. In these capacities, the design and implementation of the Foundation's EMCRO Project in 1975 and the demonstration project to which your draft refers have been under my personal medical direction.

The draft, in my opinion, quite correctly points to a need for closer attention to drug review. However, there are some alternative methodologies that should be considered to those offerred. From our vantage point, we would offer the thought that the PSRO should be the prime coordinating body for this type of review. In evaluating this alternative you might consider:

1. The overall objective is to safeguard the patient. In any system one must have capability to identify concerns and the ability to implement constructive action.

   Your draft proposal nicely outlines the programs of the past where state agency review, pharmacist review and nurses' review have all left something to be desired. Conspicuously missing is practicing physician involvement and consequently, no potential for peer interaction exists. The PSRO has the organization for providing this needed participation.

   Our own experience in the PSRO demonstration project would also bear this out. Our physicians and pharmacists committee evaluated review information and identified concerns. The concerns were then relayed to facility medical directors by Foundation physicians. The facility medical director, in turn, developed corrective action programs.

2. Public Law 93-642 allows for PSRO assumption of review responsibility. This law stresses elimination of duplicatory activity. Assuming PSRO assumption of this responsibility, it is logical to believe that efforts such as drug review should be part of the PSRO program.

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Currently, the Colorado PSRO has, in concert with Colorado's Departments of Health, Social Services and Institutions, developed a program under which basic SNF and ICF review is conducted by the PSRO. We are enthusiastic about the effort and envision an ability to increase physician involvement, influence state legislation, and improve the health management process. If you are interested, our staff can provide you with information about this endeavor.

3. A PSRO provides both a local focus for problem solving and physician participation. It could also provide better control over criteria, recruitment of reviewers, the performance of reviewers, and the vital constructive action. It could also allow interacting other related review information. This coordination might well make the review process more efficient and less costly.

I believe these three arguments present a case for further exploration of the concept that the PSRO should be used to develop and demonstrate a superior system of drug review in the nursing home. Some further comments relative to the draft recommendations are in order.

Criteria and standards issues are of great importance. The Colorado criteria, which are cited, are SCREENING GUIDELINES. As such, they are designed to help identify questionable patterns of care, for further use in the peer review process. They are not criteria that can generally be used on an individual case basis. I therefore would question the wisdom of compiling available criteria, such as ours, and using them as some form of national standard. In all probability, our Foundation would elect to not participate in further efforts to design such a federal "cookbook".

Utilization of the National Professional Standards Review Council should go beyond the criteria area. They can give valued leadership an alternative review mechanism and most importantly in the whole area of peer review and corrective action.

The final two recommendations are sound. Of course, a PSRO alternative review system might necessitate minor modifications to adapt to local needs.

A final thought; your office's interest in promoting quality of care is stimulating. In this area of limited fiscal resources it is heartening to see your concern for quality issues. The other side of the equation is, of course, COST. The cost-benefits of review should, of course, be scrutinized in any developing review methodology. Additionally, many of us believe that there exists a huge waste of dollars in the drug utilization area. Any review program must address cost as well as quality. Perhaps the PSRO program provides the best available tool for impacting both quality and cost issues. Colorado would like to try.

We appreciate the opportunity to comment on your draft and hope the observations are of some use. Should you desire any additional background information, please feel free to contact us.

Sincerely,

Kenneth A. Kahn, M.D.

Kenneth A. Kahn, M.D.
Associate Medical Director
Long Term Care Department

cc: Ray G. Witham, M.D.
Robert B. Sawyer, M.D.
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