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STATEMENT OF
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BEFORE THE
SELECT COMMITTEE ON AGING
UNITED STATES HOUSE OF REPRESENTATIVES

ON

REVIEWS OF MEDICAID-FINANCED
DRUG THERAPY IN NURSING HOMES

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Mr. Chairman and Members of the Committee, we are pleased to be here today to discuss our report on the problems in reviews of Medicaid-financed drug therapy in Medicaid nursing homes which is being released today. In summary, our report says

—Medicaid nursing home patients taking certain classes of prescription drugs have not had their drug regimens monitored through various tests in accordance with criteria developed by Professional Standards Review Organizations (PSROs) and others.

—In five of the six States visited (Georgia, Iowa, Kansas, Massachusetts and Texas), our random sample of nursing home patients indicated that 82 percent had not received the recommended tests under the most liberal available criteria for frequency. In the sixth state (California), where our sample was curtailed, a similarly high incidence of non-compliance was noted.

—Findings by PSROs evaluating long term care in Colorado and Utah closely parallel our findings.

To better assure the health and safety of patients, the Department of Health and Human Services (HSS) 1/ in 1974 established nursing home standards requiring monthly review of patient medications by a pharmacist or registered nurse. We found that the medication review process is not working adequately. As discussed in the report, the inadequacies in the medication review process are principally due to the two following factors.

1/ Department of Health, Education, and Welfare prior to May 4, 1980.

--HHS has not provided adequate information on monitoring and use of drugs--particularly the frequency with which tests should be performed; and

--HHS has not provided adequate medication review guidelines to pharmacists and nurses.

We also found that pharmacists making medication reviews at many of the homes we visited were also filling prescriptions for the patients. We believe this creates a potential conflict of interest because the pharmacists have a financial disincentive to reduce patient drug utilization.

BACKGROUND

Drugs play a major role in the treatment of nursing home patients and because of the potential hazards of drug therapy, we selected for study the medication review process. Medication review involves determining whether the patient needs the drug and whether it is properly administered, effective, and safe. In medication review, the pharmacist or nurse is assisting the attending physician by assuring that the drugs are properly administered and by bringing to the physician's attention any questions regarding the effectiveness and safety of the drugs.

The elderly, as a group, take more drugs than younger persons and elderly nursing home patients take more drugs than the noninstituionalized elderly. A 1976 HHS report shows that 54 percent of nursing home patients were receiving six or more drugs at a time, with some receiving

as many as 23 drugs. A sizable proportion of drugs prescribed for the elderly are long-term maintenance drugs, used primarly for controlling chronic diseases. The elderly generally are more susceptible to adverse drug reactions, interactions, or lack of therapeutic response because of the number of drugs they take. They are also more sensitive to some drug actions and drugs often accumulate in the body. The elderly frequently have more than one chronic medical condition which adds to the risk because a drug used to treat one condition may be contraindicated due to the presence of other conditions.

Our approach in this review was to determine (1) whether the medications taken by selected patients were being monitored and (2) the general medication review procedures followed by pharmacists and registered nurses. Our work was done at 68 randomly selected nursing homes in six states — California, Georgia, Iowa, Kansas, Massachusetts and Texas. The six states were selected to provide geographical dispersion and because about 30 percent of all nursing homes are located in them. Work was discontinued in California before all the homes selected were visited when it became apparent that results would not be substantially different from those in the other five states. Therefore, as explained in the report, the results from California could not be included in the statistical projections we made.

MONITORING PATIENT DRUG THERAPY

Pharmacists and registered nurses charged with making medication reviews rely heavily on information shown on drug labeling. However,

labeling generally does not have sufficient specific information on how drugs should be monitored—particularly the frequency with which tests should be performed—or on the implications of using multiple drugs affecting the same body system. More specific information regarding monitoring and use of some drugs is available from PSROs and other sources, but this information is not readily accessible to medication reviewers. We believe that HHS should disseminate to medication reviewers the drug monitoring and usage criteria which has been developed by PSROs and others and promote further development of drug criteria by PSROs.

Using the more specific information available from PSROs and other sources as criteria, we found that a high percentage of patients taking certain drugs were not receiving recommended tests under the most liberal available criteria for frequency. We also found that, in a few instances, patients either received combinations of tranquilizers or sedatives which one PSRO characterized as "inappropriate utilization" or had medical conditions which, according to drug labeling, should have precluded the use of certain drugs taken.

We determined at each nursing home visited whether randomly selected patients taking one or more of ten drugs received laboratory tests or other diagnostic tests with the frequency recommended by either selected PSRO guidelines or guidelines prepared under an HHS contract by the University of Minnesota School of Pharmacy. The Social Security Act requires PSROs to evaluate the quality or suitability of long term care

delivered to Medicaid and Medicare patients. While many PSROs have not developed a long term care evaluation program, we identified five PSROs which had developed evaluative criteria which include procedures for monitoring drugs. The HHS contracted for the guidelines developed by the University of Minnesota to assist nursing homes in identifying patterns of problems in drug utilization. Both criteria sources developed their guidelines with input from a variety of health professionals, including practicing physicians. The criteria represent general guidelines to be used by reviewers—who are normally not physicians—to identify possible problems. In those instances in which criteria are not met, the developers of the criteria 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 the unique health conditions and drug responses of the individual patient are taken into account.

The ten drugs for which we obtained monitoring criteria from PSROs or the University of Minnesota guidelines were in one of four classes of drugs—diuretics (used to reduce body fluids), cardiac stimulants, hematinics (used to treat anemia), and anti-hypertensives (used to treat high blood pressure).

The monitoring criteria specified that certain procedures, such as blood tests or electrocardiograms, be performed with various frequencies. Since not all the criteria sources recommended the same monitoring procedures or frequency of performance for the ten drugs, we used the most

lenient criteria in analyzing the sample patients. For example, we used the longest interval between tests as our standard where sources differed as to frequency of a test.

About 82 percent of the 349 patients we sampled in Georgia, Iowa, Kansas, Massachusetts and Texas either did not receive the tests or did not receive them as frequently as recommended by the most lenient criteria available. By projecting our sample, we estimate that about 81 percent of the approximately 49,000 patients in the five States who took these drugs were not monitored as recommended by the criteria. Some patients took one or more of the ten drugs for periods up to 26 months and did not receive the appropriate tests, which generally were supposed to be performed every 6 to 12 months.

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 criteria. On the other hand, two of the PSROs used as criteria sources also found high rates of noncompliance with screening criteria on some of the same drugs after the added step of physician peer review showed that deviations were not justified. Because the incidence of non-compliance with the screening criteria in our sample closely parallels, or is lower than, the incidence of non-compliance identified by PSROs after peer review, we believe that our findings fairly reflect the general pattern of use of these ten drugs in nursing homes in the five States.

We also analyzed the medications of patients randomly selected from all Medicaid participants in nursing homes in the States of Georgia, Iowa, Massachusetts and Texas. This sample did not include Kansas because we added this sample after our work in Kansas had been completed. Using prescription drug labeling information as criteria, we found that about 6 percent of the patients in our sample received contraindicated drugs, which FDA defines as "* * *those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." The following is an example from the cases 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. 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.

For this same sample, we found that about 3 percent received simultaneously three or more central nervous system (CNS) depressing drugs--tranquilizers and sedatives--although one of the PSRO's guidelines indicated this was "inappropriate utilization." The following is an example of the use of multiple CNS depressing drugs selected from the cases reviewed.

A 79-year old woman took several different drugs that depress the CNS. Some drugs were tranquilizers or sedatives which have as a primary effect the depression of the CNS. Other drugs she took, such as antihistamines, depress the CNS as a side effect. At any given time, she took anywhere from one to five CNS depressing drugs per day, although she usually took three in addition to the other drugs in her regimen. 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.

We believe that most of the drug monitoring problems we identified are due to the medication reviewers not having a single source of accurate, complete information on drugs. An HHS-funded study pointed out that the most widely used source of drug information by physicians is the drug labeling and we learned the same to be true for pharmacists and registered nurses making medication reviews at the homes we visited. We also found that labeling information for drugs included in our review did not always contain sufficient specific information on how the drugs should be monitored or be used in conjunction with other drugs. For example, labeling information for some drugs recommended that certain tests be performed but the frequency was stated in vague terms such as "frequently" or "periodically". Drug labeling for the CNS-depressing drugs we analyzed normally contained little guidance concerning the use of more than one CNS depressant, other than the admonition to use caution.

In commenting on our draft report, HHS stated that 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 and that it considered the majority of drug labeling to be adequate in that context. HHS also stated that current FDA regulations require labeling for each drug to contain information on contraindications for its use, warnings, precautions, adverse reactions, dosage and administration. According to HHS, it is impossible to include in labeling warnings regarding the use of each drug in combination with other drugs because of the myriad combinations and permutations that are possible with the number of drugs presently available.

Although HHS stated in its comments to our draft report that drug labeling is adequate for "medically well informed professionals", we do not believe that it is adequate for pharmacists and registered nurses making medication reviews. Studies over the last 10 years, including some sponsored by HHS, have reported that important drug information is not always readily accessible or that the information which is available—including FDA approved drug labeling—is not always complete and objective. These studies reported that health professionals, including physicians, were in need of better information than that provided in drug labeling and that one solution would be development of a drug compendium. In 1979, legislation was introduced in the Congress which would authorize HHS or a private organization to develop such a comprehensive drug guide. HHS is supporting this legislation although, in commenting on our

draft report, it stated that it is unrealistic and possibly undesirable, to expect that all information about drugs will ever be contained in one source.

We believe that a drug compendium could be of great value in meeting the drug information needs of pharmacists and registered nurses engaged in medication review, assuming that the document will include relevant information supplemental to that shown in drug labeling. For example, the compendium should include known drug interaction information which FDA considers to be impractical to include in drug labeling. Development of a compendium will be a formidable task which which probably will take several years to complete because about 5,000 prescription drugs had FDA marketing approval as of December 1979. About 500 of these drugs are taken by nursing home patients. However, drugs taken by 16 to 58 percent of these patients are in only ten classes of drugs. For example, 58 percent of the patients take laxatives, 51 percent take analgesics (pain relievers), and 16 percent take anti-infectives. Criteria on the monitoring and use of some of these drugs has been developed by PSROs and others. We therefore recommended that, pending publication of a drug compendium, HHS issue those criteria which have been developed by PSROs and others to provide immediate assistance to those pharmacists and nurses making medication reviews in nursing homes.

HHS generally agreed with our recommendation that PSRO criteria be disseminated, with the stipulation that the criteria be identified as screening criteria and not be inflexible.

MEDICATION REVIEW GUIDELINES ARE INADEQUATE

HHS standards require that nursing homes have a pharmacist or registered nurse review the medications of each patient monthly. However, HHS has not adequately defined the scope of these reviews--matters such reviewing the patient's medical record, interviewing and observing the patient, and determining whether specific types of potential problems exist. In this absence of a definition of the scope of medication review, the pharmacists and nurses are left to develop their own interpretations of what should be done. At the nursing homes we visited the scope of review varied considerably and at many of these homes the scope appeared to be inadequate.

The HHS standards for skilled and intermediate care state as follows regarding medication review.

> Skilled care (42 CFR 405.1127(a))
>
> A pharmacist must review the drug regimen of each patient at least monthly and report any "irregularities" to the medical director and administrator.
>
> Intermediate care (42 CFR 442.336)
>
> A registered nurse must review medications monthly for each resident and notify the physician if "changes are appropriate".

Although HHS did not clarify the standards, it did take certain other actions which may have helped to indoctrinate some pharmacists and nurses. About six months before the medication review standards were published in 1974, HHS's Public Health Service issued contracts to

two organizations to provide training programs and materials on matters relating to nursing home patient medications. The University of Minnesota developed those guidelines and model criteria for conducting drug utilization reviews which we discussed earlier in this statement. However, this information did not receive wide distribution. The American Pharmaceutical Association (APhA), a national society of pharmacists, (1) conducted a series of workshops and seminars on institutional pharmaceutical services, including medication review, (2) prepared a curriculum for schools of pharmacy to provide similar training to students, (3) developed and is promoting a home study course for pharmacists on monitoring drug therapy, and (4) developed and is promoting a teaching guide for use by pharmacists in training nursing home staffs in pharmacy services. Neither APhA nor HEW knows how many pharmacists or nurses involved in medication review have been exposed to the training courses or materials.

The APhA medication review training materials include specific review methodology such as procedures for identifying potential problems, check lists, and coordination with nursing home staff. According to APhA, the purpose of this material is to orient pharmacists and others to the medication review process. APhA stated that the set of procedures outlined are neither standardized nor required in all instances, and that 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, these training materials imply certain

minimim coverage which can reasonably be expected of the reviewer regardless of specific review procedures followed. The APhA training materials indicated that the scope of medication review made by pharmacists should include:

—Reviewing the patient's medical records.

—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.

—Notifying as appropriate the physician or nursing home staff when medication problems are indentified.

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.

We interviewed pharmacists having medication review responsibilities at some of the homes visited to determine the scope of their reviews. The scope of review described by about half of these pharmacists was less than that suggested by the APHA training materials. For example, some pharmacists were either not reviewing patient medical records or were not doing doing so routinely while while others reviewed the records but did not consider or did not make recommendations on the need for tests or the physician's choice of drugs. The reasons given by these pharmacists can generally be placed in the following three categories: (1) they did not consider themselves to be qualified for various reasons, including lack of clinical training or inadequate information on some drugs, (2) their personal concept or interpretations of the scope of medication review was different, including some who believed that certain matters, such as choice of drugs, were the responsiblity of the nurse or physician, and (3) concern over possible resentment by attending physicians.

We believe that HHS needs to establish minimum standards as to scope of medication review by both pharmacists and registered nurses and to also assure that medication reviewers are apprised of acceptable review methodology. In response to our draft report, both HHS and APhA stated that they are opposed to any standards which would require reviewers to follow a certain system regarding method of review. APhA agreed, however, that HHS should do more to apprise nursing homes and health care personnel of the many possible--but not required--elements of a medication review which

are available. We concur with HHS and APhA that reviewers should not be required to follow a certain system or method; however, we believe that HHS can define the scope of medication review coverage while still allowing reviewers the latitude to choose specific review methodology to be followed.

We also 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 regarding their roles and provide them with a clear understanding of their responsibilities. While issuance of these guidelines and standards will not solve all problems in 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.

SOME PHARMACISTS HAVE POTENTIAL CONFLICTING INTERESTS

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

interest because the pharmacists making the medication reviews would have a financial disincentive to recommend the discontinuance of or reduction in dosage of the drugs he or she is selling.

In 1977, HHS drafted guidelines which encouraged separation of pharmacy consultant services and drug vendor services in those geographic areas where it is possible and feasible. The guidelines, however, have never been issued in final form because of unresolved issues regarding payment for drugs. In our opinion, HHS should issue regulations requiring separation of the medication review component of consultant services from drug vendor services whenever feasible and deal separately with the unresolved payment issues.

In commenting on our draft report, HHS said 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." HHS also stated that separation of the two functions would, because of inadequate reimbursement for medication reviews, seriously limit the ability of nursing homes to secure any meaningful review of records. According to HHS, reimbursement for dispensing services are supporting, to a large degree, the medication review activity. APhA apparently agrees with HHS that reimbursement for medication review is inadequate and, while acknowledging that a potential conflict exists, the Association believes the best method of preventing an actual conflict from occurring is to adequately compensate pharamacists for nondispensing services.

We do not agree with either HHS or APHA. Our recommendation is addressed to the financial incentive which may contribute to less than adequate 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 overcome while a third—financial conflict of interest—should be ignored.

HHS'S PROPOSED REVISED STANDARDS

At the request of your committee, we have analyzed the provisions of HHS's proposed revised nursing home standards which deal with medication review. These proposed revised standards, applicable to both levels of care, provide for the following (42CFR 483.25(h)).

—A pharmacist must review the drug regimen of each patient at least monthly

—Any "irregularities" must be reported to the attending physician or the director of nursing

—A record of drug regimen reviews must be prepared by the pharmacist and maintained in the facility

The major changes in the standards are that pharmacists rather than nurses will be required to review intermediate care patient medications and that reviewers will be required to keep written records of medications reviews. HHS's introductory comments to the proposed standards state that pharmacist's review was extended to intermediate care patients because research had shown that the clinical pharmacist does make an impact in skilled nursing facilities.

Special medication review studies conducted by clinical pharmacists have demonstrated certain impacts, such as reduction in the number of drugs taken by patients and early detection of adverse effects. Therefore, extending the pharamacists review to intermediate care patients could result in some positive impact on the health and safety of patients. However, as discussed in our report, we believe that in order to assure that this impact will result, HHS needs to assist pharmacists by clearly defining the scope of review, providing medication review training and other guidance and disseminating drug monitoring and use criteria. What is missing from the proposed revised standards, and which we feel is extremely important to include, is a complete and clear definition of the scope of medication review.

We believe that the new requirement that a record of drug regimen reviews be kept is also an improvement. We found that not all medication reviewers were maintaining such records. We believe these records will be of particular value in evaluating medication reviews made at each home.

Mr. Chairman, this concludes our prepared testimony. We'll be happy to answer any questions you or other members of the Committee may have.