

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PRESCRIPTION DRUG USE
IN NURSING HOMES**

Report 3

**A Pharmaceutical Review
and
Inspection Recommendations**



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EXECUTIVE SUMMARY

PURPOSE

To assess the extent and appropriateness of pharmaceutical use by selected Texas nursing home residents and to describe pharmacists' concerns about drug use.

BACKGROUND

The primary goal of drug therapy for nursing home patients is to maintain and improve, to the extent possible, the patient's functional capacity and quality of life. The Omnibus Budget Reconciliation Acts (OBRA) of 1987 and 1990, in recognition of this, require the regulation of certain drugs in nursing homes and the establishment of drug utilization review programs for nursing home residents. Provisions of the OBRA 1990, while not required for all nursing homes, also clearly establish Congress' desire to involve pharmacists more actively in patient care. Broad oversight of the drug therapy requirements for the nursing homes is performed by consultant pharmacists hired to perform a monthly medication review for each resident. Yet, several recent studies suggest that the use of inappropriate or contraindicated drugs is a contributing factor to the high health care costs in the elderly population. It is important to understand that reports of possible "inappropriate" use of medications are somewhat a matter of opinion. Ultimately, for nursing home patients, it is either the patient's attending physician or the facility's medical director who determine what is appropriate care. This includes prescribing medications to meet patients' needs.

We undertook this inspection, using three different approaches, to provide insight into several issues related to prescription drug use in nursing homes. These issues are addressed in three reports, of which this is the third. The first report describes prescription drug use in Texas nursing facilities; the second report discusses medication use concerns expressed by a nationally representative sample of consultant pharmacists. This third report provides the results of a pharmaceutical review (conducted by independent pharmacists with whom we contracted for this purpose) of 254 sampled Texas nursing home patients. Additionally, this final report presents recommendations addressing the issues and concerns raised collectively by all three reports issued as part of this coordinated inspection.

FINDINGS

Overall, contracted pharmacists' reviews consistently identified the same problems and concerns for patients as were raised by our analysis of Texas data and the national survey of consultant pharmacists. This finding underscores the need for strengthening medication reviews and improving medication prescribing, administration, and monitoring practices in nursing homes.

Quality of Care Issues

Contracted medication reviews revealed potentially serious concerns with residents' drug regimens.

20 percent of the reviewed patient records identified patients receiving at least one drug judged inappropriate for their diagnoses. Additionally, patients' records indicated some residents were taking medications potentially contraindicated by their diet requirements, plans of care, or assessments.

16 percent of patients were receiving, without a prescription in their records, drugs for which prescriptions are generally required. Further, 23 percent of the patients were prescribed medications for which the records showed no orders or receipts to indicate the patient actually received the medication.

Approximately 20 percent of residents received at least one drug considered by experts to be inappropriate for use by the elderly.

Some patients' records indicate they may be experiencing unnecessary adverse medication reactions as a result of inadequate monitoring.

21 percent of patients were receiving drugs which may sometimes negatively interact with other drugs in their regimen.

Nearly one-third of patients were receiving more than one drug from the same class, sometimes a potential hazard. Drugs from the same class may produce similar side effects which can be additive and need to be carefully managed. Yet, 19 percent of all records indicate no monitoring for efficacy.

Shortcomings of Medication Reviews

Resident medication records are often incomplete, making it difficult or impossible to identify or confirm potential drug regimen problems.

31 percent of patients' records were not sufficiently complete to allow contract pharmacists to make determinations concerning the appropriateness of medications prescribed for patients' diagnoses.

Contract pharmacists identified several patients whose prescribed medications may have contributed to falls, depression, and constipation. However, due to insufficient records, they were unable to pinpoint or eliminate the patient's drug regimen as the cause.

Often the contract pharmacists were unable to determine whether a patient had received a monthly drug regimen review during the sampled time period.

Thorough contracted medication reviews required much more time than the usual review times reported by nursing home consultant pharmacists. Allotting more time for conducting reviews appears to help in detecting more medication concerns.

Contract pharmacists' reviews averaged 50 minutes, which is considerably longer than the times consultant pharmacists expend doing medication reviews (averaged 5-10 minutes per monthly review with initial reviews taking 15-20 minutes).

The contract pharmacists identified medication problems or concerns for 20 percent of the patients which had not been identified by the nursing home consultant pharmacists' reviews.

RECOMMENDATIONS

Medication problems and concerns raised collectively by the three coordinated reports of this inspection demonstrate the need for stronger monitoring and more positive enforcement of existing regulations and required reviews of medication usage in nursing homes. Therefore, we recommend that the Health Care Financing Administration:

- Continue to monitor and encourage reductions in the use of potentially inappropriate prescription drugs in the elderly nursing home population;
- Work with other Federal and State agencies to identify and analyze reasons for the rapid escalation in costs and claims for certain types of drugs used in nursing homes (i.e., gastrointestinal, psychotherapeutic, cardiac, cardiovascular, and anti-infectives);
- Strengthen the effectiveness and impact of medication reviews conducted by consultant pharmacists in nursing homes;
- Require nursing homes to ensure that the curriculum for required on-going, in-service training for personal care staff (nurse aides) includes information on how to recognize and report signs of possible contraindications, adverse reactions, or inappropriate responses to medications;
- Strengthen and enforce coordination and communication among the involved healthcare team members in nursing homes; and
- More vigorously pursue enforcement of resident health outcomes.

COMMENTS ON THE DRAFT REPORT

We solicited comments from agencies within the Department of Health and Human Services which have responsibilities for policies related to Medicare and Medicaid and long term care. We also requested input from several national organizations representing

the interests of nursing homes, patients, or providers. We appreciate the time and efforts of those providing comments.

Departmental Comments

Within the Department, we received comments on the draft reports from the Health Care Financing Administration (HCFA) and the Assistant Secretary for Planning and Evaluation (ASPE). Both agencies concurred with the recommendations; HCFA emphasized the need for further studies to assess the extent of continued use of potentially inappropriate drugs, other avenues of possible cost savings related to drugs, and the need to determine and understand the potential sources of the escalating costs and claims for certain types of drugs used in nursing homes. The final reports reflect several clarifications or changes based on their suggestions. The full text of each agency's comments is provided in Appendix D.

Comments from External Organizations

We also received comments from the following external organizations: American Health Care Association; American Association of Homes and Services for the Aging; American Medical Directors Association; American Society of Consultant Pharmacists; and National Association of Boards of Pharmacy. Most of the associations concurred with one or more of the recommendations within each of the inspection reports. All commentors support the need for better communication and coordination between nursing home staff and other healthcare providers, training nurse aides, and understanding the implications of nursing home medication services and associated costs.

Several organizations questioned the methodology used in this inspection, particularly for the consultant pharmacist survey. However, as with any evaluation, there are always some limitations in how data and information can be obtained, given time and other resource constraints. Further, while we acknowledge that a survey of this nature introduces some bias and subjectivity, we also believe that the survey of consultant pharmacists provides us with an up-close view of what is happening with prescription drug use in nursing homes. Moreover, the results of the consultant pharmacist survey are consistent with our results from our two other methodologies.

Some comments expressed concerns about the use of the term, "inappropriate." As explained previously, use of this term in reporting concerns with a patient's medication regimen are somewhat a matter of opinion. The evidence provided in these three reports does not prove that any one prescription was improper, but that closer examination is warranted. Also, while the use of such a drug may be supported by physician orders in individual cases, use of the drug, in general, is likely to be considered inappropriate.

Some comments addressed the implications of broadening Federal oversight. There is clear concern about the responsibility for medication issues being the responsibility of the physician, not the nursing home. Further, some organizations expressed concern that these particular issues did not result in direct recommendations about the physician's role

for nursing home patients' medication regimens. We felt that further examination of this area is warranted before recommending changes which would impact so many entities involved in the process.

In conclusion, we believe the three reports collectively, and each using a different approach, strongly indicate that the intent of the provisions of the OBRA Acts concerning prescription drug usage are not being clearly fulfilled. Further, HCFA has authority to correct and enhance quality of care for nursing home patients. The recommendations we present attempt to facilitate the initial steps of this effort, and to address some concerns evidenced in the reports and received comments. While we recognize that great strides have been made to meet the OBRA requirements, we believe further effort remains by all the players involved (HCFA, associations and their members, nursing homes, and residents and their families) to further improve quality of care for nursing home patients.

The full text of each organization's comments is provided in Appendix E.

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INTRODUCTION

PURPOSE

To assess the extent and appropriateness of pharmaceutical use by selected Texas nursing home residents and to describe pharmacists' concerns about drug use.

BACKGROUND

Long-Term Care and Prescription Medications

Medicaid is the primary public program for long-term care assistance for the elderly and disabled. Long-term care is one of the largest and fastest growing needs of the elderly. Of the \$39.8 billion in program expenditures for care of this population in fiscal year 1995, 73 percent (\$29.1 billion) went for nursing home stays.¹

Payments for prescription drugs represent a large portion of Medicaid's expenditures for nursing facilities. Medicaid provided services for 1.7 million nursing home residents in fiscal year 1995 at an average cost per bed from \$600 to \$1000 per year.² This suggests that Medicaid paid between \$1 billion and \$1.7 billion to provide prescription drugs to residents of long-term care facilities. This could be as much as 16 percent of total Medicaid prescription drug expenditures.

Potential Health and Cost Problems

Several recent studies suggest that inappropriate use of prescription drugs by the elderly creates the potential for serious health problems and the increased risk for wasted hundreds of millions of Federal dollars annually in medication and hospitalization costs. One study estimated that the percentage of hospitalizations of elderly patients due to adverse medication reactions to be 17 percent, almost 6 times greater than for the general population.³ Further, an expert panel of pharmacists estimates that the injuries resulting from failed drug therapy result in approximately 100,000 hospitalizations and a cost of \$77 billion each year.⁴

According to the Food and Drug Administration (FDA), the elderly, about 13 percent of the U. S. Population, account for over one-third of the "adverse drug experiences" reported by pharmacists, physicians, and other health professionals. These figures translate to 30,000 hospitalizations and \$25 billion in costs among the elderly.⁵ Much of this cost is paid by the elderly population, but a large portion of it is borne by Federal health care programs including Medicare and Medicaid. Clearly, Federal programs as well as our senior citizens are paying the high cost of failed drug therapy.⁶ Not only do the elderly use prescription drugs more than any other age population, they also tend to be taking several drugs at once, increasing the probability of adverse drug reactions.^{7,8} The elderly may also eliminate these medications from their system less efficiently than those younger due to decreased bodily functions.

Studies also suggest more subtle effects of inappropriate medication usage among the elderly, such as loss of cognitive or physical function and the potential for increased falls. Researchers have concluded that a number of prescription drugs used by the general population should not be prescribed for elderly patients (see Appendix A). Yet, the General Accounting Office reported that the Health Care Financing Administration's (HCFA) Office of the Actuary in 1992 found 17.5 percent of the 30 million senior citizens receiving Medicare benefits had received at least one medication inappropriate for use by the elderly. Today, many equally effective drugs are available which present fewer risks for elderly patients.⁹

Regulation and Control of Prescription Drug Use in Nursing Facilities

Omnibus Budget Reconciliation Act of 1987

As part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), Congress required the regulation of certain drugs in nursing facilities. On October 1, 1990, HCFA implemented regulations which hold nursing facilities accountable for monitoring medication usage.¹⁰ Significant requirements for pharmaceutical care of nursing home residents include provisions regarding Pharmacy Services (drug regimen review), Quality of Care (drug therapy), Resident Rights (self-administration of drugs), Resident Assessment, and Infection Control. Additionally, physicians must justify the use of antipsychotic drugs based on specific diagnoses and observe specific parameters within which these drugs may be used.

Nursing Home Patients, Medications, and OBRA 1987

Each nursing home patient must receive necessary nursing, medical, and psychosocial services allowing him/her to attain and maintain the highest possible functional status. This status is defined by a comprehensive assessment and plan of care which each patient receives upon admission to the home and as "substantive" changes occur in the patient's health status. To ensure each patient receives the necessary quality care, the law and subsequent regulations also recognize the value of medication therapy by defining certain limitations:

- 1) patients must not receive unnecessary medications;
- 2) patients cannot be prescribed antipsychotic drugs unless they are appropriate for a specific patient condition;
- 3) patients prescribed antipsychotic drugs will receive gradual dose reductions, or behavioral programming in an effort to discontinue the drugs (unless clinically contraindicated); and
- 4) the home must have no significant medication error rates and patients must also have no significant medication errors.

To ensure these requirements are met, the States and HCFA are responsible for performing routine facility surveys. To guide the medication-related part of these reviews, HCFA developed "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews," standards to assist in assessing the quality of drug regimen

reviews and for enforcing performance, and "Surveyor Methodology for Detecting Medication Errors," provides the surveyor with a mechanism to evaluate the outcome of the entire medication distribution system and to ensure the facility error rate is less than five percent and that residents are free of risk from significant medication errors. Several States have proven the five percent error rate to be a target figure now more easily obtained and, additionally, HCFA is considering lowering this target rate for hospitals to two percent. The HCFA also released revised interpretive guidelines relating to medication usage in nursing facilities which provide tools for identifying medication errors, and even include a list of specific drug therapy circumstances which may constitute potential drug irregularities. None of these standards is routinely shared by HCFA with consultant pharmacists who conduct the nursing home pharmaceutical reviews.

As a final step in the implementation of OBRA 1987, in July 1995 HCFA released new survey and enforcement procedures. Changes include the use of new quality of life guides for the patient, group, and family interviews; a protocol for non-interviewable residents; closer cooperation between the State survey agency and the ombudsmen programs; and better information for providers, including information to help them compare their patients to residents of other nursing facilities across the region, State, or nation. Again, none of these potentially useful changes were disseminated to consultant pharmacists.

Omnibus Budget Reconciliation Act of 1990

The provisions of Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) clearly demonstrate Congress' desire to involve pharmacists more actively in patient care by refocusing pharmacists from a product oriented role to one involving clinical practice responsibilities for reducing potential drug therapy problems. While not required for nursing homes in compliance with drug regimen review requirements (specified in 42 CFR 483.60), practicing pharmacists are expected to:

- 1) prospectively review the patient's present drug therapy and medical condition with proposed drug therapy;
- 2) appropriately intervene with the prescriber on the patient's behalf when inappropriate drug therapy has been prescribed; and
- 3) as an outcome of their review, counsel patients on the proper use and storage of medication and how to alleviate or prevent potential therapeutic problems related to medication usage.

Under OBRA 1990, the State Medicaid plan must provide for a review of potential drug therapy problems due to therapeutic duplication; drug-disease contraindications; drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs); incorrect drug dosage or duration of drug treatment; drug-allergy interactions; and clinical misuse. Thus, OBRA 1990, in essence, requires a certain standard of practice for Medicaid patients. While this regulation and the statute at section 1927(g)(1)(D) of the Social Security Act preclude any Federal action to expand this law to apply directly to nursing home patients, most States have extended coverage to all patients, including those of health facilities.¹¹ One major component of this law, patient counseling, has increased

both the role and the responsibility of the pharmacist in patient healthcare understanding, planning, and outcomes, which, arguably, should be extended to all health care environments.

Role of Consultant Pharmacists

Pharmacists, through their education and training, should be able to identify any serious concerns related to medication prescribing and administration practices which, when corrected, yield a positive impact on the quality of life for nursing home patients. To ensure compliance with the OBRA regulations, nursing facilities are expected to employ consultant pharmacists. These consultant pharmacists are supposed to conduct monthly reviews of the drug regimen of each facility resident to determine whether the prescription drugs ordered for that individual are appropriate based on the OBRA guidelines. Consultant pharmacists are also required to:

- 1) determine that drug records for each resident are in order;
- 2) establish a system to record receipt and disposition of prescription drugs;
- 3) offer advice and instruction in all other areas of pharmacy services; and
- 4) report any irregularities they discover in a resident's drug regimen to the attending physician and director of nursing.

Some of the potential benefits of the consultant pharmacist role in nursing homes are the reduction of excessive medication usage, improvement in patient quality of care, and decreased cost for medication usage. Pharmacists may also help medical and nursing personnel significantly improve medication therapy for patients in nursing homes which, in turn, can help reduce total health care costs,¹² particularly for those changes resulting from fewer medications being taken, more appropriate medications being prescribed, and fewer costly adverse reactions being experienced. Yet, there are no standards for either drug regimen reviews or drug utilization reviews provided by HCFA to consultant pharmacists. There are only minimal conduct requirements for medication reviews and no standardized process, common definitions, administration, or quality assurance process for this requirement. Thus, there is no acceptable means for comparing reviews, findings, or patient outcomes between nursing homes or consultant pharmacists, let alone between States.

Patient Assessment and Plan of Care

As part of the nursing home's assessment process for each patient entering the facility, the required Resident Assessment Instrument provides a standardized process for reviewing each patient's functional capacity. This, in turn, leads to the individual Plan of Care specific to that patient's identified needs. These two documents could be of considerable help to consultant pharmacists in monitoring patient medication for desired care outcomes. However, many consultant pharmacists reported in the prior phase of this inspection that resident assessments and care plans are not routinely used as part of their medication reviews.¹³

The Resident Assessment Instrument includes tools which could facilitate a pharmacist's medication review for a nursing home patient. One collects a minimum amount of information needed to evaluate each patient (the Minimum Data Set); the other identifies any conditions that may require further assessment ("triggers" from the Resident Assessment Protocols). As part of the assessment, section O reviews patient medications. The HCFA developed a drug class reference list of specific drugs to ensure that categorization and identification of patient drugs is standardized for surveyors and other personnel using the Resident Assessment Instrument (to ensure everyone is defining a drug in the same class). Again, these tools are not routinely shared with consultant pharmacists nor are they required for use in conducting patient medication reviews.

The Minimum Data Set Drug Class Index groups specific drugs a patient may be taking into the four OBRA categories (antianxiety drugs, antidepressants, antipsychotics, and hypnotics) and adds diuretics. The HCFA list also identifies which specific drugs in the five categories are inappropriate for the elderly. It should be noted that the Beers list (Appendix A) includes the same drugs as the HCFA list. However, the Beers list is more extensive and includes drugs of other types which are also inappropriate for the elderly (i.e., certain pain medications, medications for blood circulation or blood pressure, etc.). Yet, neither the HCFA list nor the Beers list are required or suggested for use by consultant pharmacists as part of their medication review process.

Physicians Determine What Is Appropriate For Each Patient

Reports of possible "inappropriate" use of medications are somewhat a matter of medical opinion. Ultimately, for nursing home patients, it is either the patient's attending physician or the facility's medical director who determine what is appropriate care. This includes prescribing medications to meet patients' needs. Once an individual is admitted to a nursing home, the *attending physician* routinely participates in the ongoing care of that patient, along with the other nursing home staff. The American Medical Association defines several functional responsibilities for physicians with patients in long term care facilities, including examining the patient upon admission; initiating, developing, and overseeing the implementation of a comprehensive plan of care; maintaining medical records; and participating in quality assurance reviews when possible.¹⁴ The physicians are the primary persons to whom nursing staff look for identification and delineation of care for specific medical conditions, including prescribing of any necessary medications.

Generally, the nursing home's *medical director* is expected to participate in a foundation of activities relating to the care of nursing home patients. These include participating in the formulation and review of care policies, infection guidelines, and *pharmacy protocols*; provision of in-service education for staff; and attendance at a variety of facility committee meetings (e.g., quality assurance). This role includes coordinating visits to patients by other health care professionals, including attending physicians. Further, the medical director is expected to intervene if an attending physician is negligent in visiting patients or providing quality care.

OBRA 1987 requires that the pharmacist report any identified irregularities to the attending physician of the patient and the director of nursing and that these reports be "acted upon." Yet, the regulations do not specify several important aspects of reporting any pharmacist's concerns:

1. how (i.e., in what format or in which patient records, such notification will be provided);
2. whether the medical and nursing personnel are required to provide an explanation for acceptance or rejection of the pharmacist's concerns;
3. guidance to medical, nursing, or pharmaceutical staff as to what constitutes "acting on" reported concerns or irregularities; and
4. no specified format or record location for acceptance or rejection of pharmacists' concerns by medical or nursing personnel.

It should be noted that regardless of any reported concerns by the consultant pharmacist, it is the physician's legal responsibility to order medication changes, not that of the director of nursing. We do not minimize the difficulties physicians encounter in meeting the medication needs of the most typical nursing home patient - the disabled or infirm elderly person. Much available literature details the complexities of diagnosing and the unique challenges of prescribing medications for the elderly.

Challenges of Prescribing Medications for the Elderly¹⁵

Some disorders, which occur in the general elderly population with characteristic symptoms and signs, present *unusual features* or, conversely, present *without usual features*. Problems usually restricted to the elderly include stroke, decubitus ulcers, metabolic bone disease, degenerative osteoarthritis, hip fracture, dementia syndrome, falling, Parkinsonism, and urinary incontinence. Further, the usual signs may be replaced with less specific ones, such as refusal to eat or drink, falling, incontinence, acute confusion, increasing dementia, weight loss, and failure to thrive. Multiple disorders in the elderly complicate and interfere with diagnosis and treatment of the presenting illness. Depression is probably the most common psychiatric disorder of persons over the age of 65. Other conditions which become more common with age and which may present themselves atypically include organic psychoses, paranoid states, hypochondriasis, and suicide.

Aging changes bodily organs and systems, causing less efficient functioning, and thus, affecting the elderly person's responses to medications. Any person over the age of 65 has the potential for increased side effects, overdose, and/or diminished efficacy for a minimum of 13 drug classes, such as antibiotics, antihypertensives, cardiac medications, psychiatric medications (antidepressants, tranquilizers, hypnotics, etc.), or pain relievers. Also, most clinical trials and studies on specific medications are usually performed using younger people; the result can be drug treatment standards often hazardous to the elderly. Thus, while the elderly may use the same drugs as younger persons, the effects can be far different.

Research identifies many indicators relating to adverse medication outcomes, some of which more directly pertain to nursing home patients. These include a patient having five or more medications in their drug regimen, having 12 or more doses per day, having more than three concurrent disease states, and the presence of drugs requiring monitoring. Each of these are fairly common indicators for most nursing home patients.

Thus, the typical elderly nursing home patient may require different care skills and knowledge of health care professionals than those required to treat the non-nursing home populations with acute care problems. The primary goal of drug therapy in chronic care is to maintain and improve, to the extent possible, the patient's functional capacity and quality of life.

METHODOLOGY

Focus of Our Series of Reports

In 1996, we undertook a project to assess the extent and appropriateness of drug use by Medicare and Medicaid residents of nursing facilities. This project, conducted in three phases, involved 1) a database analysis of the extent of prescription drug use by Texas nursing home residents eligible for both Medicare and Medicaid; 2) a national survey of consultant pharmacists to assess their role in identifying and reducing drug use problems in nursing facilities; and 3) a pharmaceutical review of patients' records to determine the extent and appropriateness of prescription drugs utilized by a random sample of Texas nursing home residents.

The first report, "An Introduction Based on Texas" (OEI-06-96-00080), provides specific information concerning actual drug expenditures and identifies the types of drugs being used in Texas nursing facilities. The second report, "An Inside View by Consultant Pharmacists" (OEI-06-96-00081), focuses on the problems and concerns raised by consultant pharmacists based on a national mail survey. The third phase of this inspection involved a pharmaceutical desk review of the medical records of a sample of Texas nursing home residents, the results of which are included in this report.

This inspection was initiated as part of Operation Restore Trust, an initiative involving multi-disciplinary teams of State and Federal personnel seeking to reduce fraud, waste, and abuse in nursing facilities and home health agencies, and by durable medical equipment suppliers. The initiative focused in five States (California, Florida, Illinois, New York, and Texas).

Data analysis of prescription drug payments was purposely limited to Texas based on 1) the availability of Medicaid data and planned identification of the Medicare and Medicaid population in the State by HCFA and the Office of the Inspector General (OIG), 2) designation as a demonstration site for Operation Restore Trust, and 3) the large number of nursing facilities in Texas, approximately eight percent of long term care facilities in the nation. Texas also ranks third in the nation for total Medicaid spending. Such data was not readily available for other States. Thus, Texas was the selected site for the first

and third phases of this inspection. While we recognize that State operations concerning nursing homes can vary greatly in their interpretation and enforcement of policies, we believe the concerns identified in Texas will be generally common to many States.

Focus and Methodology of This Report

Through consultation with pharmacists and nursing surveyors from the Health Care Financing Administration and with representatives of the American Society of Consultant Pharmacists, we identified nursing home records (administrative and medical) pertinent to conducting a desk review for a patient's pharmaceutical regimen. We selected for review 254 nursing home patients residing in Texas nursing homes during the period January 1 to July 1, 1995. The nursing homes provided each patient's most recent assessment and plan of care, as well as their drug regimen, payment records, and medical records. Any additional records to assist in a patient's medication review were also requested from the nursing home. Appendix B identifies both the letter of request to the nursing home and the specific records requested for each selected patient.

We contracted with Integrated Healthcare Auditing and Services, Inc. (IHAS) to provide pharmacists experienced in performing patient medication reviews for nursing home patients. While there are many methods of performing a medication review for nursing home patients, we asked pharmacists to conduct both a general review (an overview of each patient's drug therapy) and a problem-oriented review (focused on each patient's medical problems and their individual responses to their drug therapy). Essentially, these pharmacists assessed the appropriateness and impact of each patient's drug regimen.

As no standardized tool is available for the conduct of individual patient medication reviews, we developed one with help from experts to facilitate the process of recording findings for each patient under review (see Appendix C). Additionally, for any patient review involving medical concerns beyond the pharmacist's expertise, a physician having geriatric and pharmacological experience was contracted by IHAS to make final medical determinations. We do not generalize the contract pharmacists' findings to encompass all Texas nursing home patients, choosing instead to present the findings only in relation to the 254 patients reviewed.

This review was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

QUALITY OF CARE ISSUES

Overall, contracted pharmacists consistently identified the same problems and concerns for patients as those raised by our analysis of Texas data and the national survey of consultant pharmacists. Medication problems and concerns raised collectively by the three coordinated reports of this inspection demonstrate the need for stronger monitoring and more positive enforcement of existing regulations and required reviews of medication usage in nursing homes.

Medication reviews reveal potentially serious concerns with residents' drug regimens.

- 20 percent of residents received at least one drug judged *inappropriate for the diagnoses in their records*. Of these, 32 percent received three or more inappropriate drugs, and five percent had seven or more. For some, the inappropriate drugs are rather benign, such as acetaminophen or milk of magnesia. However, others received psychoactive drugs such as diazepam and Prozac or drugs normally used to treat cardiac or cardiovascular problems and which are likely to pose greater dangers when inappropriate for a patient's condition. Additionally, based on available patient records, contract pharmacists identified patients taking medications potentially inappropriate according to the patients' diet requirements (17 percent), plans of care (8 percent), or by the resident assessments (6 percent).
- 16 percent of residents had *no prescription in their records* to support one or more of the drugs in their regimen for which a prescription is generally required. This finding reflects those drugs identified in the medical records, including the medication administration records, provided by the nursing homes. At a minimum, this finding shows a problem with incomplete nursing home records. In the worst case, it shows that patients are receiving drugs not ordered.

The drugs represent nearly 8 percent of the total drugs identified through this review and range in type from gastrointestinal preparations and laxatives to antianxiety drugs and antidepressants. Additionally, 14 percent of residents are taking over-the-counter medications without physician orders. Most of these were for pain control or gastrointestinal problems (acetaminophen, Zantac) which may interact with other prescribed medications being taken. Further, 23 percent of the patient records indicated patients having been prescribed medications for which the records showed no orders or receipts to indicate the patient actually received the medication.

- Contract pharmacists identified 20 percent of residents whose records indicated use of at least one drug considered generally to be *inappropriate for the elderly*. These inappropriate drugs were identified by matching drugs identified in each patient's

records against a list of 20 drugs generally considered inappropriate for elderly patients by a panel of experts (see Appendix A). Some of these drugs are inappropriate because of being outdated and having been replaced by more efficacious and less risky alternatives as well as their unique effects on the elderly. As with any medication, one should be aware that some medical situations might warrant the use of these drugs. Of the patients identified, 21 percent had two or more such possibly inappropriate drugs. This confirms findings of the first report of this series¹⁶ in which a comparison of Texas drug records with the list found that 20 percent of residents received one or more of the listed drugs.

There are many challenges to prescribing and monitoring medications for elderly nursing home patients. Multiple disorders in the elderly combined with patients having five or more medications in their drug regimen, having 12 or more doses per day, having more than three concurrent disease states, and taking medications which require monitoring greatly complicate identification of possible adverse effects of a patient's medication regimen. This complex picture is further compounded by the need to balance what could be inappropriate medications against the benefits of relieving or treating diseases which warrant such usage for the enhancement or maintenance of an individual's quality of life.

Arguably, pharmacists' professional education gives them valuable expertise and clinical knowledge concerning pharmacotherapy. Critical to this expertise and extremely important for the nursing home residents is monitoring the effects of medication usage, either for maintaining or improving a patient's health status or to identify any effects of medications or disease which may undermine such improvement or maintenance.

- Findings of the contract pharmacists indicate that some patients may be experiencing *unnecessary adverse medication reactions as a result of inadequate monitoring* of medications. Some of the patients' records identified medications which possibly contributed to their constipation (14 percent), falls (8 percent), or depression (5 percent). For 9 percent of the patients, their records indicated other adverse effects possibly caused by medications. Patients' records indicated a potentially serious lack of necessary monitoring:
 - 19 percent of the patients' records gave no indication of monitoring for medication side effects when required;
 - 23 percent of the records had no indication that required lab testing had been performed;
 - 19 percent of the records did not indicate that necessary physical assessments had been conducted.
- According to available records, 21 percent of residents received *medications which may sometimes interact negatively with other drugs* included in their medication regimens. For example, if a patient received both glyburide (oral antidiabetic agent) and levothyroid medications, the glyburide may decrease the necessary effects of the

thyroid medication. However, some negative interactions can be expected when a patient has a complex diagnostic picture. Yet, medication interactions may sometimes be so severe as to be absolutely contraindicated; medications may represent poor therapeutic choices if other therapy choices are available; or the risk of a negative interaction may be justified when there are no other treatment options available.

- Nearly one-third of residents received *more than one drug from the same class*, sometimes considered a potential hazard unless the drug regimen requires this combination for efficacy or to meet the multiple demands and needs of multiple disease states for which a patient may be diagnosed. Drugs from the same class may produce similar side effects which can be additive, in which case they definitely need to be carefully managed. Yet, 19 percent of the records indicate no monitoring for appropriate efficacy when warranted.

Several examples illustrate the concern raised by the contract pharmacists about patients taking multiple drugs with additive side effects that require monitoring. One example is a patient concurrently receiving nortriptyline (tricyclic antidepressant), Prozac (fluoxetine, for treatment of major depression, obsessive-compulsive disorder, etc.), and haloperidol (haldol, antipsychotic agent). Another example was a patient taking three medications all of which can cause sedation, lorazepam (anti-anxiety agent also used for insomnia), cyproheptadine (antihistamine), and perphenazine (antipsychotic agent). Another patient was taking two forms of salicylates (aspirin) which may result in toxicity; one taking cimetidine (H₂-receptor antagonist used for treatment of upper gastrointestinal problems such as an ulcer) which may decrease absorption of iron salts or increase the effects of temazepam (sleep aide) also required by the patient; and another was taking both haldol and amitriptyline for insomnia.

SHORTCOMINGS OF MEDICATION REVIEWS

Resident medication records are often incomplete, making it difficult or impossible to identify or confirm potential drug regimen problems.

In many of the reviewed cases, there were a number of records in which our contracted pharmacists were unable to find sufficient supporting information to make any definitive determination.

- As previously stated, 20 percent of residents had clearly documented use of drugs inappropriate for the recorded diagnoses. However, another 31 percent of patients' records were insufficiently complete to allow the pharmacists to make determinations concerning the appropriateness of prescribed medications for indicated diagnoses. An incorrect diagnosis, or no easily available diagnosis, forces pharmacists to work in a void. Incomplete records could cause drug regimen problems to be significantly understated.

Nursing homes are required to maintain each patient's most recent assessment, plan of care, and the doctor's orders which provide much of the necessary information for a

pharmacist to identify any factors which may negatively affect a patient's medication regimen. Thus, between these three documents, pharmacists should be able to make a determination. However, the contracted pharmacists often were unable to make a decisive determination because of insufficient records.

- Also previously discussed, the contractors identified several patients for whom prescribed medications may have contributed to constipation, falls, or depression. These situations are often attributable to inappropriate use or dosages of certain drugs. However, the contract pharmacists were unable to link these events directly to adverse drug reactions because of incomplete resident records (i.e., daily nursing notes were not requested, unavailable individual patient drug reviews, lack of orders, etc.). For the same reason, they were unable to rule out a resident's drug regimen as the cause of these conditions.

It should be noted that consultant pharmacists may find themselves in a similar situation of not having all the necessary records to fully conduct their reviews. Additionally, by not being in the nursing home on a routine basis, they may lack familiarity with the location of critical information in a facility's files.

Often, contract pharmacists were unable to determine whether a patient had received a monthly drug regimen review during the sampled time period.

Nursing homes did not provide copies of patient's monthly drug regimen reviews. Reasons cited included:

- 1) not being able to obtain the individual report from the facility's consultant pharmacist. Most consultant pharmacists provide services to more than one facility and their drug regimen review records may be kept at home or in the contracted company's office, rather than at the nursing home.
- 2) administrative changes in personnel and multiple record locations. New employees are sometimes uncertain as to where certain patient reports are maintained. Because there is no requirement to file the drug regimen reports in each patient's clinical record in the facility, reports may be maintained in numerous possible locations.
- 3) nursing homes sometimes only maintain a summary report of concerns. The facility may not require their consultant pharmacist to provide individual patient reports, choosing instead to have a summary report which only identifies patients for whom the consultant pharmacist has some concern.
- 4) drug regimen reviews were not conducted as required.

Our contracted medication reviews required much more time than the usual review times reported by nursing home consultant pharmacists. Allotting more time for conducting reviews can help detect more medication concerns.

As previously discussed, medication reviews for nursing home patients can be extremely complex due to the number of primary and secondary diagnoses patients may have as well as the number of medications being prescribed. Contract pharmacists reported patients having an average of three primary and three secondary diagnoses and receiving an average of ten medications. They reported completing each patient's medication review in an average time of 50 minutes (a few reviews took as little as 20 minutes). Yet, direct responses from consultant pharmacists indicated they spend an average of 5-10 minutes on each patient's monthly drug regimen review, with most initial reviews taking 15-20 minutes.

The contract pharmacists' lengthier, more in-depth record reviews identified medication problems or concerns for 20 percent of the patients which had not been previously identified by the nursing home consultant pharmacists. Their concerns included lack of monitoring for efficacy; drugs which were clearly inappropriate for use by elderly individuals; inappropriate method of administration (i.e., crushing of sustained action drugs); medications inappropriate for diagnoses; medications being received on schedule with a duplicate available "as needed" (PRN); some PRN medications not having prescriptions; extending duration of drug use beyond the timeframe ordered; providing medications for which the patient has allergies; and medications being ordered for dosages other than those the patient received.

Further complicating regular medication reviews can be the number of over-the-counter medications being used by the nursing home patients. This record review indicates most patients (82 percent) use over-the-counter drugs and nearly 17 percent of these are being used without physician orders. Our previous report found that a serious weakness in medication reviews is that many consultant pharmacists said they do not review use of over-the-counter (OTC) drugs.¹⁷ The principal reasons stated for such non-review are that nursing homes do not allow OTC drugs without prescriptions, that nursing staff check patients' rooms for any non-prescribed medications, and that the pharmacists do not have sufficient time to do the reviews and therefore are unable to discuss medication regimens with patients.

RECOMMENDATIONS

Based on the collective concerns raised in this report and the two other reports resulting from this inspection, "An Introduction Based on Texas" (OEI-06-96-00080) and "An Inside View by Consultant Pharmacists" (OEI-06-96-00081), we recommend that HCFA work with the States and others to improve the quality of prescription drug care in nursing homes. To accomplish this objective, HCFA should:

- 1. Continue to monitor and encourage reduction in the use of potentially inappropriate prescription medications by the elderly nursing home population.¹⁸**
- 2. Work with other interested government entities, such as the Assistant Secretary for Planning and Evaluation and the Agency for Health Care Policy and Research, to:**
 - a. Identify and analyze reasons for and the appropriateness of cost escalation for certain types of drugs used in nursing homes (i.e., gastrointestinal, psychotherapeutic, cardiac, cardiovascular, and anti-infectives)¹⁹ and
 - b. Examine resident and facility-specific characteristics and drug utilization data to better understand the factors contributing to the differences between nursing homes in the costs of prescription medications used by patients.
- 3. Strengthen the effectiveness and impact of medication reviews conducted by pharmacists in nursing homes by:**
 - a. Providing guidance to medical, nursing, and pharmaceutical personnel on handling notifications about medication concerns;²⁰
 - b. Requiring pharmacists to consult patient assessments and plans of care in the conduct of their medication reviews;
 - c. Reviewing and updating routinely Appendix N of the Survey/Certification protocol; the Drug Class Index of the Minimum Data Set, Section O; Appendix P, guidelines for psychopharmacologic medications used in long term care facilities; and any other related medication policy and procedures²¹ and ensure that consultant pharmacists routinely conduct drug regimen reviews using these protocols as one set of available tools for improving their reviews but also for helping to ensure they conduct reasonably complete reviews. It may be that HCFA could require nursing homes hiring or contracting with pharmacists to provide these tools; and
 - d. Encouraging prescribing physicians to provide clinical outcome expectations for medications prescribed and requiring pharmacists to monitor for these expectations.²²

- 4. Enforce and enhance HCFA's training requirement of personal care staff (nurse aides) (i.e., aides' training curriculum should include information on how to recognize and report behavioral signals or signs of possible contraindications, adverse reactions, or inappropriate responses to medications).²³**
- 5. Strengthen and enforce coordination, communication, and patient documentation in nursing homes by:**
 - a. Exploring the feasibility of requiring nursing facilities to maintain in one central location all records pertinent to a patient's medical care;
 - b. Requiring consultant pharmacists to document each patient's medication review and resulting actions; and
 - c. Requiring that pharmacists' concerns always be reported to the attending physicians and nursing home medical directors, as well as to the Directors of Nursing.
- 6. More vigorously pursue enforcement of positive resident health outcomes. As part of this pursuit, HCFA should require pharmacist's direct input to achieving optimal clinical outcomes for residents (i.e., fewer falls or pressure sores as well as less frequent urinary incontinence, which can all be exacerbated by certain psychopharmacological, cardiovascular, and other drug therapies).²⁴ Options for HCFA to consider:**
 - a. Encouraging consultant pharmacists, nursing home medical staff, and physicians to become more familiar with HCFA's defined quality of care indicators which are related to pharmacy services and which may enhance pharmaceutical patient outcomes;
 - b. Encouraging consultant pharmacists to interact with (counsel and inform) patients as part of their medication reviews; and
 - c. Including in State and Federal surveys, process-focused reviews of pharmacists' recommendations and subsequent actions by appropriate medical and nursing personnel, and the resulting clinical outcomes for the patients.

COMMENTS ABOUT DRAFT REPORTS

We solicited comments from agencies within the Department of Health and Human Services which have responsibilities for policies related to Medicare and Medicaid and long term care. We also requested input from several national organizations representing the interests of nursing homes, patients, or providers. We appreciate the time and efforts of those providing comments.

Departmental Comments

Within the Department, we received comments on the draft reports from the Health Care Financing Administration (HCFA) and the Assistant Secretary for Planning and Evaluation (ASPE). Both agencies concurred with the recommendations; HCFA emphasized the need for further studies to assess the extent of continued use of potentially inappropriate drugs, other avenues of possible cost savings related to drugs, and the need to determine and understand the potential sources of the escalating costs and claims for certain types of drugs used in nursing homes. The final reports reflect several clarifications or changes based on their suggestions. The full text of each agency's comments is provided in Appendix D.

Comments from External Organizations

We also received comments from the following external organizations: American Health Care Association; American Association of Homes and Services for the Aging; American Medical Directors Association; American Society of Consultant Pharmacists; and National Association of Boards of Pharmacy. Most of the associations concurred with one or more of the recommendations within each of the inspection reports. All commentors support the need for better communication and coordination between nursing home staff and other healthcare providers, training nurse aides, and understanding the implications of nursing home medication services and associated costs.

Several organizations questioned the methodology used in this inspection, particularly for the consultant pharmacist survey. However, as with any evaluation, there are always some limitations in how data and information can be obtained, given time and other resource constraints. Further, while we acknowledge that a survey of this nature introduces some bias and subjectivity, we also believe that the survey of consultant pharmacists provides us with an up-close view of what is happening with prescription drug use in nursing homes. Moreover, the results of the consultant pharmacist survey are consistent with our results from our two other methodologies.

Some comments expressed concerns about the use of the term, "inappropriate." As explained previously, use of this term in reporting concerns with a patient's medication regimen are somewhat a matter of opinion. The evidence provided in these three reports does not prove that any one prescription was improper, but that closer examination is

warranted. Also, while the use of such a drug may be supported by physician orders in individual cases, use of the drug, in general, is likely to be considered inappropriate.

Some comments addressed the implications of broadening Federal oversight. There is clear concern about the responsibility for medication issues being the responsibility of the physician, not the nursing home. Further, some organizations expressed concern that these particular issues did not result in direct recommendations about the physician's role for nursing home patients' medication regimens. We felt that further examination of this area is warranted before recommending changes which would impact so many entities involved in the process.

In conclusion, we believe the three reports collectively, and each using a different approach, strongly indicate that the intent of the provisions of the OBRA Acts concerning prescription drug usage are not being clearly fulfilled. Further, HCFA has authority to correct and enhance quality of care for nursing home patients. The recommendations we present attempt to facilitate the initial steps of this effort, and to address some concerns evidenced in the reports and received comments. While we recognize that great strides have been made to meet the OBRA requirements, we believe further effort remains by all the players involved (HCFA, associations and their members, nursing homes, and residents and their families) to further improve quality of care for nursing home patients.

The full text of each organization's comments is provided in Appendix E.

ENDNOTES

1. Health Care Financing Administration, BDMS, Division of Program Systems, 1996.
2. Keitz, Todd. "10 Things You Should Know About the Long Term Care Market." *Medicinal Marketing and Media*. 30(5):42-46. May 1995.
3. Beard, Keith. "Adverse Reactions as a Cause of Hospital Admission in the Aged," *Drugs & Aging*, Vol. 2, No. 4 (July/Aug. 1992), pp. 356-67.
4. Published October 9, 1995, in the *Archives of Internal Medicine*, the data further illustrates that while spending one dollar to purchase prescription drugs, Federal and State governments also spend another dollar to correct the problems caused by misuse of those drugs.
5. General Accounting Office. "Prescription Drugs and the Elderly: Many Still Receive Potentially Harmful Drugs Despite Improvements." Letter Report GAO/HHES-95-152. July 24, 1995.
6. Knowlton, Calvin H. Statement before the Senate Special Committee on Aging, Hearing on Drugs and the Elderly, Washington, D. C. March 28, 1996.
7. Inappropriate use of medications can take a number of the following forms: drug-drug interaction; drug-age contraindication; drug-allergy contraindication; drug-disease contraindication; incorrect drug dosage; incorrect duration of drug therapy; and less effective drug therapy.
8. Spore, Diana L., P. Larrat, et al. "Inappropriate Drug Prescriptions for Elderly Residents of Board and Care Facilities." *American Journal of Public Health*, March 1997, Vol. 87, No. 3, pp. 404-409.
9. Beers, Mark, Joseph G. Ouslander, Irving Rollingher, et al. "Explicit Criteria for Determining Inappropriate Medication Use in Nursing facility Residents." *Archives of Internal Medicine*, Vol. 151(Sept. 1991), pp. 1825-32.
10. 42 CFR Sec 483.60.
11. Perri, M., J. Kotzan, L. Pritchard, et al. "OBRA 90: The Impact on Pharmacists and Patients." *American Pharmacy*, February 1995, Vol. NS35, No. 2, pp. 24-28.
12. Nelson, Arthur A. "The 'Smoking Gun' in OBRA 90." *Pharmacy Times*, February 1993, pp. 49-58.
13. Office of Inspector General, Office of Evaluation and Inspections, "Prescription Drug Use in Nursing Facilities: An Inside View by Consultant Pharmacists" (OEI-06-96-00081), November 1997.

14. Fanale, R. H., et al. "The Nursing Home Medical Director," *Journal of the American Geriatrics Society*, 1989, 37(4), pp. 371-373.
15. Merck Manual, 15th edition.
16. Office of Inspector General, Office of Evaluation and Inspections, "Prescription Drug Use in Nursing Facilities: An Introduction Based on Texas" (OEI-06-96-00080), November 1997.
17. Office of Inspector General, Office of Evaluation and Inspections, "Prescription Drug Use in Nursing Facilities: An Inside View by Consultant Pharmacists" (OEI-06-96-00081), November 1997.
18. This can be accomplished at the State level by assuring the inclusion of nursing home residents in the automated prospective drug utilization review programs already in place. At the nursing home level, State and Federal surveyors, consultant pharmacists employed as a requirement of OBRA 1987, and physicians serving as medical directors or primary care physicians should be reminded of the dangers associated with these drugs and directed to continue to actively pursue a reduction in their use. Finally, similar analysis of data from additional States should be undertaken to further assess the extent of the continued use of these contraindicated drugs.
19. We understand that new and more effective products may be more costly and may be the most appropriate for certain patients' diagnoses. However, this may be only one reason for an increase in certain drug costs. In light of concerns expressed in the medical literature, further investigation is warranted to determine whether some of these drugs are medically necessary.
20. This should include defining what constitutes both "acting on" concerns of any healthcare team member, including pharmacists, and "documentation of actions taken" in records readily accessible to nursing home and other State/Federal staff (i.e., in the patient's clinical record).
21. Include both drugs about which there are utilization concerns (H2 antagonists, non-steroidal anti-inflammatories, narcotics, antibiotics and anti-infectives, and gastrointestinals) and drugs which in many instances may be inappropriate for use by elderly persons.
22. We recognize that most clinical expectations are clearly indicated by the prescribed medication, it may not be reasonable to expect that those outcomes have been clarified for the remaining members of the healthcare team.
23. While we do not believe nurse aides should be able to identify specific probable causes for changes they observe, they should be sufficiently aware that those changes may be reflective of possible clinical problems. As part of HCFA's required on-going training of personal care staff (nurse aides), and as pharmacists

are either directly or indirectly currently employed by the nursing homes to perform drug regimen reviews, pharmacists could provide the necessary in-service training on the recognition of possible behavioral signals or signs of potential contraindications, adverse reactions, or inappropriate responses to medications. However, HCFA could explore cost-effective alternatives to pharmacists providing this training.

24. Nursing homes, like physicians, have a major responsibility for resident quality of care. This includes efforts to ensure, promote, and encourage necessary communication and corrective actions for health concerns raised by any healthcare team member. Clearly, pharmacists performing medication review services, either as nursing home employees or contractors, are an integral part of the healthcare team.

APPENDIX A

20 Drugs Experts Consider Inappropriate for the Elderly

The 20 drugs listed below were judged generally inappropriate for elderly patients by a panel of experts. The panel's results and methodology, published in 1991 and used consistently since that time, indicate that these drugs should normally not be used with elderly patients. However, they stress that there could be some medical situations in which use of these drugs would be appropriate. Further, it should be noted that this list constitutes a minimum of drugs not considered appropriate for the elderly and could be revised to include others.

Medication	Use	Comment
Amitriptyline	To treat depression	Other antidepressant medications cause fewer side effects
Carisoprodol	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity; potential for toxic reaction is greater than potential benefit
Chlordiazepoxide	As a (minor) tranquilizer or antianxiety medication	Shorter-acting benzodiazepines are safer alternatives
Chlorpropamide	To treat diabetes (a hypoglycemic agent)	Other oral medications have shorter half-lives and do not cause inappropriate antidiuretic hormone secretion
Cyclandelate	To improve blood circulation	Effectiveness is in doubt; no longer available in the U.S.

Medication	Use	Comment
Cyclobenzaprine	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity; potential for toxic reaction is greater than potential benefit
Diazepam	As a (minor) tranquilizer or antianxiety medication	Shorter-acting benzodiazepines are safer alternatives
Dipyridamole	To reduce blood-clot formation	Effectiveness at low dosage is in doubt; toxic reaction is high at higher dosages; safer alternatives exist
Flurazepam	As a sleeping pill (a hypnotic)	Shorter-acting benzodiazepines are safer alternatives
Indomethacin	To relieve the pain and inflammation of rheumatoid arthritis	Other nonsteroidal anti-inflammatory agents cause less toxic reactions
Isoxsuprine	To improve blood circulation	Effectiveness is in doubt
Meprobamate	A (major) tranquilizer (used for anxiety)	Shorter-acting benzodiazepines are safer alternatives
Methocarbamol	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity; potential for toxic reaction is greater than potential benefit

Medication	Use	Comment
Orphenadrine	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity; potential for toxic reaction is greater than potential benefit
Pentazocine	To relieve moderate to severe pain	Other narcotic medications are safer and more effective
Pentobarbital	As a sleeping pill and to reduce anxiety (hypnotic)	Safer sedative-hypnotics are available
Phenylbutazone	To relieve the pain and inflammation of rheumatoid arthritis	Other nonsteroidal anti-inflammatory agents cause less toxic reactions
Propoxyphene	To relieve mild to moderate pain	Other analgesic medications are more effective and safer
Secobarbital	As a sleeping pill and to reduce anxiety (hypnotic)	Safer sedative-hypnotics are available
Trimethobenzamide	To relieve nausea and vomiting	Least effective of available antiemetics

Source:

Beers, Mark, Joseph G. Ouslander, Irving Rollinger, et al. "Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents." *Archives of Internal Medicine*, Vol. 151(Sept. 1991), pp. 1825-32.

APPENDIX B

Nursing Home Patient Records Requested

For an identified review period, nursing homes for the selected 254 patients were asked to provide any patient record, including the initial Patient Assessment and Plan of Care, related to the initial admit of the patient to the facility. For the time period related to each patient's indicated stay period in the nursing home, nursing homes were also asked to provide any subsequent changes as well as the following items specific to the time period under review:

- Patient Assessment/Evaluation(s)
- Plan(s) of Care
- Medication Administration Records
- Physician Prescriber Orders
- Physician Prescriber Progress Notes
- Behavioral Monitoring Sheets
- Laboratory Orders
- Laboratory Reports
- Incident or Accident Reports
- Nursing Monthly Summary Progress Report(s)
- Nursing Quarterly Summary Report(s)
- Drug Regimen Review(s)
- Consultant Pharmacist Review and Remarks Sheet(s)
- Consultant Pharmacist Quarterly Report(s)
- Consultant Pharmacist Correspondence (related to patient reviews)

Facilities were also asked to provide any additional documentation including assessments by other providers which may impact medication therapy (i.e., diet, therapists, etc.).

The table below provides a sample of the letter sent to the nursing homes for the required records.

Letter to Nursing Homes for Required Records

Dear Nursing Home Administrator:

The Office of Evaluation and Inspections, part of the Office of Inspector General, conducts national program evaluations. Although other Inspector General offices conduct fraud investigations and audits, our function is to provide policy makers and managers with analysis and recommendations for improving programs, policies, and regulations involving Medicare and Medicaid. We are currently involved in an evaluation to assess the extent and appropriateness of drug use by patients in nursing homes.

Your facility has been randomly selected for our review of medication usage in Texas nursing homes. Under authority granted to the Office of Inspector General, by 42 CFR Section 3525, we are requesting that you provide patient records for one or a few randomly selected residents. These residents are *Medicare eligible beneficiaries for whom Medicaid paid for the stays in your facility during 1995*. Attachment A identifies the resident or residents (by name, their Health Insurance Claim Number (HICN) number, and the stay date(s)) for whom we require copies of applicable patient records.

To ensure that we have sufficient information to conduct our review, copies of the nursing home records should include any records related to the patient's stay as indicated on the attached list (generally, a 3-month period). Additionally, we need any patient specific record for the first/initial admission to your facility. The following records are requested for each resident:

1. **Patient Assessment/Evaluation** for the first/initial admission to your facility
2. **Patient Assessment(s)/Evaluation(s)** for the period specified in Attachment A (*hereafter referred to as the "stay"*)
3. **Plan of Care** for the first/initial admission to your facility
4. **Plan(s) of Care** for the period related to stay
5. **Medication Administration Records (MAR)** for the period related to stay
6. **Physician Prescriber Orders** for the period related to stay
7. **Physician Prescriber Progress Notes** for the period related to stay
8. **Behavioral Monitoring Sheets** for the period related to stay
9. **Lab Orders** for the period related to stay
10. **Lab Reports** for the period related to stay
11. **Incident or Accident Reports** for the period related to stay
12. **Nursing Monthly Summary Progress Report** for the period related to stay
13. **Nursing Quarterly Summary Report** for the period related to stay
14. **Drug Regimen Report to Administrator** for each month for the period related to stay
15. **Drug Utilization Report** for the period related to stay
16. **Consultant Pharmacist Review and Remarks Sheet** for each specified patient for the period related to stay
17. **Consultant Pharmacist Quarterly Report** for the period related to stay
18. **Consultant Pharmacist Correspondence** to/from physician(s), Director of Nursing, or other regarding patient's medication therapy or associated issues including lab issues related to medication(s) for the period related to stay
19. **Any patient evaluations** conducted by other professional personnel impacting medication therapy (e.g., Dietary Evaluation, Psychiatric/Psychologic evaluation, Social Evaluation, Dental, etc.) for the period related to stay

If you determine that other information would be valuable to our assessment of drug usage, please provide this information, as well.

Instructions

- ▶ All copies must be complete, clear, and legible.
- ▶ All copies should clearly indicate the name or Medicare Health Insurance Number (HICN) at the top left corner of each page.
- ▶ All copies should indicate, at the top left corner of each page, the type of document you are providing (e.g., DUR Page 1 of 4, CP Review Sheet for October, etc.) This is to ensure that the medical consultants performing the review will be able to easily identify the type of information they are reviewing.
- ▶ The attached form (*Attachment B*) must be filled out as a summary sheet **for each patient for each stay** indicating which forms you have copied in relation to the indicated stay and are sending to this office. In a few cases this might necessitate duplicate copying of some records. However, it is very important that all records associated with each patient's stay be a complete, stand alone package.
 - If forms are unavailable, indicate this in the space provided, giving the reason for not providing that form (e.g., not maintained in this facility; unable to locate; etc.).
 - If additional or other types of records are provided, but not listed on the attached form, add the type to the list under the category "Other."
- ▶ Please mail the requested information to this office **by November 18** using first class or overnight mail.

If you have any questions regarding this request, or if you will be unable to provide the requested records by **November 18**, please contact Leah Bostick or Kevin Golladay at 1/800-848-8960. Thank you very much for your assistance and prompt response.

[Appendix B to the letter is not included.]

APPENDIX C

Pharmaceutical Desk Review Form

Medical Review Screening and Certification

Patient Name: _____ DOB: _____

Patient Sample #: _____ Gender: M/F

Medicare Number: _____

Nursing Facility: _____

Medical Record #: _____

Sample Stay Period: _____ To _____ (3 months, generally)

NURSING FACILITY PATIENT DIAGNOSES

Primary Diagnosis	Secondary or Co-Morbidities
1. _____	_____
2. _____	_____
3. _____	_____

CONTINUE WITH MEDICATION SUMMARY SHEETS
COMPLETE MEDICAL REVIEW SCREENING AND CERTIFICATION



PATIENT LAST NAME _____

MEDICATION SUMMARY SHEET PATIENT SAMPLE # _____

PAGE 1 OF 4	2	3	4	*5	6a	6b	*7	8	9	10	11	12
MEDICATION NAME	NDC # FOR MEDICATION	MED ON NDC LIST BUT NOT IN RECORDS	MED IN RECORDS BUT NOT ON NDC LIST	MED INAPPROPRIATE FOR DIAGNOSIS	RX AVAILABLE	Rx SPECIFIES NO GENERIC SUBSTITUTION	M.D. ORDERS INCOMPLETE	ORDERS HAVE SPECIFIC DIRECTIONS FOR USAGE	MD ORDERS CORRECT/ CURRENT WHEN SIGNED	PRN	ORDERED	OTC
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
CODE:												
<p>"Y" FOR YES "N" FOR NO "IN" CODE FOR INSUFFICIENT INFORMATION TO MAKE DETERMINATIONS "NA" FOR NOT APPLICABLE "DN" FOR DON'T KNOW IF "Y", Use Remarks Section to explain potential or actual problem</p>												

COMPLETED BY: _____ NAME & TITLE _____ DATE: _____

PATIENT LAST NAME _____

MEDICATION SUMMARY SHEET PATIENT SAMPLE # _____

PAGE 2 OF 4	*13	14	15	16	17	*18	19	20	*21	22
MEDICATION NAME	MED INAPPROPRIATE FOR ELDERLY	DOSAGE WITHIN APPROPRIATE SUGGESTED RANGE	DOSE EXCESSIVE	DOSE INSUFFICIENT	DOSE NOT ADJUSTED TO COMPENSATE FOR REDUCED RENAL/HEPATIC FUNCTION	DOSAGE INAPPROPRIATE FOR ELDERLY	OPTIMAL DURATION	DURATION INSUFFICIENT	DURATION EXCESSIVE (LONGER THAN APPROPRIATE)	MEDICAL/MD JUSTIFICATION AVAILABLE FOR LONGER DURATION
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
CODE:										

"Y" FOR YES
 "N" FOR NO
 "IN" CODE FOR INSUFFICIENT INFORMATION TO MAKE DETERMINATIONS
 "NA" FOR NOT APPLICABLE
 "DN" FOR DON'T KNOW
 IF "Y", Use Remarks Section to explain potential or actual problem

COMPLETED BY: _____ NAME & TITLE _____ DATE: _____

PATIENT LAST NAME _____

MEDICATION SUMMARY SHEET PATIENT SAMPLE # _____

PAGE 3 OF 4	23	*25	*26	27	28	29	30	31	32	*33
MEDICATION NAME	APPROPRIATE & ACCURATE ADMINISTRATION TECHNIQUE	CORRECT ROUTE OF ADMINISTRATION	MEDICATION IS OF SAME DRUG CLASS AS OTHER MED BEING TAKEN (SPECIFY OTHER DRUG#)	NEGATIVELY INTERACTS WITH OTHER MEDS BEING TAKEN (SPECIFY OTHER DRUG#)	MAR REFLECTS DOSE AS PRESCRIBED	NECESSARY LAB TESTING FOR ROUTINE, ON-GONG MONITORING	MONITORING FOR SIDE EFFECTS	GENDER CONTRA-INDICATION	ALLERGY CONTRA-INDICATION	NEGATIVELY INTERACTS WITH DIET/FOOD
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
CODE:	"Y" FOR YES "N" FOR NO "IN" CODE FOR INSUFFICIENT INFORMATION TO MAKE DETERMINATIONS "NA" FOR NOT APPLICABLE "DN" FOR DON'T KNOW IF "Y", Use Remarks Section to explain potential or actual problem									

COMPLETED BY: _____ NAME & TITLE _____ DATE: _____

PATIENT LAST NAME _____

MEDICATION SUMMARY SHEET PATIENT SAMPLE # _____

PAGE 4 OF 4	34	35	36	*37	38	39	40	41	42	43	44	45	45
MEDICATION NAME	CONTRIBUTED TO DEPRESSION	CONTRIBUTED TO FALLS	CONTRIBUTED TO CONSTIPATION	CONTRIBUTED TO OTHER ADVERSE EFFECTS	CONTRIBUTED TO HOSPITAL STAY	MED. OVER-UTILIZED	MED. UNDER-UTILIZED	PHYSICAL ASSESSMENT FOR MONITORING MED (ie, B/P, temp, etc.)	CONTRA-INDICATED BY PLAN OF CARE	CONTRA-INDICATED BY RESIDENT ASSESSMENT OR EVALUATION	TIME FRAMES FOR LAB TESTING APPROPRIATE	MONITORING FOR EFFICACY	LESS EXPENSIVE EQUALLY EFFECTIVE MED. AVAILABLE (SPECIFY MED.)
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
CODE:													

"Y" FOR YES
 "N" FOR NO
 "IN" CODE FOR INSUFFICIENT INFORMATION TO MAKE DETERMINATIONS
 "NA" FOR NOT APPLICABLE
 "DN" FOR DON'T KNOW
 IF "Y", Use Remarks Section to explain potential or actual problem

COMPLETED BY: _____ NAME & TITLE _____ DATE: _____

Remarks Section

Use this page for additional information related to medication concerns marked in columns

MEDS#	COLUMN #	REVIEWER'S NOTES

Attach additional page[s], if needed

Medical Review Screening and Certification

After completing the Medication Summary Sheet for this patient, answer the following questions.

- 1. Did the consultant pharmacist for the nursing home identify the same concerns as you did?

YES NO
YES NO
[Handwritten marks]

If NO, which medication(s) and questions(s) were not identified? (Use numbers from the Medication Summary Sheet form to identify.) [#reflects medication & reflects column number]

Q , Comment
Q , Comment
Q , Comment
Q , Comment

REFER TO IHAS PHYSICIAN FOR CERTIFICATION. Only if you feel necessary to confirm your findings.

- 2. Did the consultant/pharmacist for the nursing home relay the concerns to the appropriate medical personnel?
YES NO

If NO, which medication(s) and question(s) did they not relay (use numbers from the Medication Summary Sheet form to identify. [#reflects medication & Q reflects column number]

Q , Comment
Q , Comment
Q , Comment
Q , Comment

REFER TO IHAS PHYSICIAN FOR DOCUMENTATION. Only if you feel necessary to confirm your findings.

- 3. Was there follow-up action taken to correct the concerns of the nursing home's consultant pharmacists?
YES NO NA
4. Was the action appropriate to correct the concerns you identified?
YES NO NA

If NO, what should have been done (that wasn't)?

[Handwritten lines]

Drug Use by Texas Nursing Home Patients
M.D. Referral/Decision Form

Patient Name: _____ Referral Date ___/___/___

Patient Sample Number: _____

Medicare Number: _____

REASONS FOR REFERRAL:

1. Pharmacist questions the following numbered items on the Medication Summary Sheet form:

[#reflects medication & Q reflects column number]

#___Q___ #___Q___ #___Q___ #___Q___ #___Q___ #___Q___

2. Incomplete File _____

3. Pharmacist unfamiliar with a particular medication _____

4. Other _____

Pharmacist Requesting Referral _____
Print Name

TO BE COMPLETED BY M.D.
(M.D. Decision)

_____ Agree with IHAS Pharmacist's Determination

_____ Disagree with IHAS Pharmacist's Determination

(Note: If the MD agrees or disagrees only in part, s/he must be specific as to each question raised by the pharmacist above).

Reason(s) for Disagree _____

M.D. Comments _____

Print M.D. Name _____

_____ M.D. Signature

Date Review Completed ___/___/___

Amount of time for review by _____ M.D.
(Minutes)

APPENDIX D

Departmental Comments About Inspection Draft Reports



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: SEP 23 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle *NMD*
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Prescription Drug Use in Nursing Facilities: An Introduction Based on Texas," (OEI-06-96-00080)

We reviewed the above-referenced report that describes the extent and appropriateness of drug use by Medicare and Medicaid residents of Texas nursing homes.

Payments for prescription drugs represent a large portion of Medicaid's expenditures for nursing homes. In fiscal year 1995, Medicaid payments for prescription drugs reached \$9.8 billion. Medicaid provided services for 1.7 million nursing home residents in the same year. Prescription drug costs are estimated to range from \$600 to \$1000 per resident. This implies that between \$1 billion and \$1.7 billion of those payments went for prescription drugs in nursing facilities. Additionally, several recent studies suggest that the use of inappropriate or contraindicated drugs is a contributing factor to the high health care costs in the elderly population.

To assess the extent of prescription drug use by dually-eligible residents, OIG obtained Medicaid data for nursing home residents in Texas for calendar years 1992-94 and the first 6 months of 1995. This data collection and extraction effort was a part of OIG's joint Texas Database Project.

The Health Care Financing Administration (HCFA) concurs with all of OIG's recommendations. Our detailed comments are as follows:

OIG Recommendation 1

HCFA should continue to monitor and encourage reduction in the use of contraindicated prescription drugs in the elderly population.

HCFA Response

We concur. This can be accomplished at the state level. However, states are not required to include nursing facility (NF) residents in the automated prospective drug utilization review (DUR) programs unless the NF is not in compliance with drug regimen review requirements specified in 42 CFR 483.60. This regulation, and the statute at section 1927(g)(1)(D) of the Social Security Act, preclude any Federal action to require DUR for drugs dispensed by NFs that are in compliance with Federal requirements. The requirements specify that states are not required to "perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with drug regimen review procedures" HCFA will continue to monitor data from states that included this population in the automated prospective DUR programs.

At the facility level, state and Federal surveyors, consultant pharmacists employed as a requirement of the Omnibus Budget Reconciliation Act of 1987, and physicians should be reminded of the dangers associated with these drugs and directed to continue to actively pursue a reduction in their use.

Most state Medicaid agencies distribute newsletters that relate concerns regarding drug problems, such as drug contraindications in the elderly population, to pharmacists and physicians in the state. Also, information sharing among state Medicaid agencies in forums such as the annual DUR symposium keeps state and Federal surveyors, consultant pharmacists, and physicians abreast of the dangers associated with contraindicated drugs and the elderly.

HCFA agrees that similar analysis of data from more states should be undertaken to further assess the extent of continued use of contraindicated drugs. HCFA will continue to act as a clearinghouse by collecting data reported by states in the DUR annual reports on this subject, and disseminating the information to facilitate data sharing among states. In addition, we encourage states that have included NF residents in their DUR programs to establish relationships with local colleges of pharmacy that may be interested in assessing the extent of the continued use of contraindicated drugs in the elderly population.

OIG Recommendation 2

HCFA and others should be aware of the significant increases in the number of claims, as well as the rapidly escalating costs for certain types of drugs (especially gastrointestinal, psychotherapeutic, cardiac, cardiovascular, and anti-infectives) used in NFs.

HCFA Response

We concur. HCFA is aware of the significant increases in the number of claims, and the escalating costs for certain drugs used in NFs in those states that report such information in DUR annual reports. HCFA will play a more active role in making state Medicaid agencies aware of trends in this area via the HCFA DUR Newsletter, scheduled for quarterly publication. The newsletter will share information we receive regarding the increase in the use of these drugs in NFs and other information relevant to DUR. We will strongly encourage states to share such information with consultant pharmacists, physicians, and all providers responsible for ensuring quality care in NFs.

In addition, HCFA would like OIG to report the extent of possible cost savings, whether they come from cheaper alternative drugs, or from the fact that drugs may not be necessary. HCFA would like to know whether the safer and more effective alternatives cost less than those drugs presently used.

OIG Recommendation 3

Further study should be undertaken, examining data about resident conditions, types of specialized care, and other facility-specific characteristics, along with drug expenditure and usage data, to better understand the factors contributing to the differences between NFs in the costs of prescription drugs used by residents.

HCFA Response

We concur. Further study in this area should be undertaken, and HCFA would like to solicit the help of organizations such as the Agency for Health Care Policy and Research to further examine this issue.



DATE: OCT 13 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Prescription Drug Use in Nursing Facilities: An Inside View by Consultant Pharmacists," (OEI-06-96-00081)

We reviewed the above-referenced report that describes consultant pharmacists' concerns about drug usage in nursing homes and their perceptions of their responsibilities for medication reviews for nursing home residents.

The Omnibus Budget Reconciliation Act of 1987 and subsequent regulations define certain limitations related to drug therapy. Among these, (1) patients must not receive unnecessary medications; (2) patients cannot be prescribed antipsychotic drugs unless they are appropriate for a specific patient's condition; and (3) prescribed antipsychotic drugs will receive gradual dose reductions or behavioral programming in an effort to discontinue the drugs (unless clinically contraindicated). Also, nursing homes must have no significant medication error rates and patients should have no significant medication errors. Oversight in the nursing homes for these requirements is performed by consultant pharmacists hired to perform a monthly medication review for each resident. As such, these pharmacists are a valuable source of information. To take advantage of their experience, OIG surveyed a statistically valid sample of pharmacists drawn from a stratified random sample of the 17,000 nursing facilities. The report represents the results of an in-depth, structured mail survey of these consultant pharmacists.

The OIG report suggests that the Health Care Financing Administration (HCFA) work with the states and other responsible entities to improve the effectiveness of medication review for patients in nursing homes. HCFA is offering the following comments to OIG's suggestions for improvement:

Informing and Documenting

HCFA will explore ways to enhance each of these suggestions to improve communication between the pharmacist and physician, but we must point out that facilities have always been required to maintain records of the pharmacist review in the facility. The January 1982 State Operations Manual transmittal which first introduced the Appendix N

guidelines stated, "A record of drug reviews must be maintained in the facility in order to demonstrate that such reviews have been performed."

The purpose of drug regimen review was to introduce current drug information into the facility and to share that information, relative to specific patients, with the medical and nursing staffs. HCFA never expected that some pharmacists would keep this information to themselves, as is apparently the case in the example OIG described on page 16 in which many facilities had trouble providing drug regimen review records because the pharmacist "had them in a different location."

State and Federal Survey and Certification

We have been endeavoring to review and update Appendix N for some time and will continue to do so in the future. We have devoted considerable time and effort (including time in obtaining physician and pharmacist input) to guidelines for psychopharmacologic medications for Appendix P (applies to long term care (LTC) facilities), and to guidelines for intermediate care facilities for the mentally retarded.

Since Appendix N was adopted, Medicare has changed its policy for payment of laboratory tests (i.e., no more orders for tests, especially multiple tests, without good clinical indications). This means any laboratory tests referred to in the revision will have to address a multitude of "clinical justified conditions," instead of time periods (in the current Appendix N) which are less difficult to define and to reach consensus.

OIG suggests that HCFA should ensure that consultant pharmacists routinely conduct drug regimen reviews according to Appendix N protocols. Appendix N comes nowhere near the scope of the pharmacology that potentially occurs in LTC facilities. Appendix N was developed to give surveyors enough information to make a reasonable judgment as to whether the pharmacist had conducted a reasonably complete job of drug regimen review. Its purpose was never intended for use by pharmacists. Unfortunately, it has been perceived by some pharmacists as the entire drug regimen review requirement.



DATE: OCT 14 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle **NMD**
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Prescription Drug Use in Nursing Facilities: A Pharmaceutical Review of Selected Texas Patients," (OEI-06-96-00082)

We reviewed the above-referenced report that examines the extent and appropriateness of pharmaceutical use by selected Texas nursing home (NH) residents and describes pharmacists' concerns about drug use. This is the third in a series of OIG reports and underscores the need to strengthen medication reviews and improve medication prescribing, administration, and monitoring practices in NHs.

The Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) and subsequent regulations define certain limitations related to drug therapy. Among these are: 1) patients must not receive unnecessary medications; 2) patients cannot be prescribed antipsychotic drugs unless they are appropriate for a specific patient condition; 3) patients prescribed antipsychotic drugs will receive gradual dose reductions or behavioral programming in an effort to discontinue the drugs (unless clinically contraindicated); and 4) the NH must have no significant medication error rates. NHs often engage consultant pharmacists to help them comply with these requirements.

The Health Care Financing Administration (HCFA) concurs with the intent of the report recommendations. Our detailed comments are:

OIG Recommendation #1

HCFA should continue to monitor and encourage reduction in the use of contraindicated prescription drugs in the elderly NH population.

HCFA Response

We concur. This recommendation refers to a paper by Beers, M.H., et al., entitled "Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents," and published in the Archive of Internal Medicine, September 1991. Adoption of these criteria as Medicare guidelines has been proposed at the staff level in HCFA.

OIG Recommendation #2

HCFA should identify and analyze reasons for the rapid escalation in costs and claims for certain types of drugs used in NHs (i.e., gastrointestinal, psychotherapeutic, cardiac, cardiovascular, and anti-infectives).

HCFA Response

We concur. We must determine the potential source of this escalation. One potential reason for increased costs is the decrease in the use of antipsychotic drugs and the increase in the use of antidepressant drugs that are used in long-term care facilities. HCFA has been encouraging the diagnosis and treatment of depression and the more conservative use of antipsychotic drugs since the early 1990s. Since most antipsychotic drugs are off-patent and generically available (thus less expensive) and the antidepressants being used are not, cost escalations could be occurring because of these factors.

OIG Recommendation #3

HCFA should strengthen the effectiveness and impact of medication reviews conducted by consultant pharmacists in NHs.

HCFA Response

We partially concur. Pharmacists have been required to conduct drug regimen reviews in NHs since 1974. Appendix N was primarily written for surveyors, but it also serves the purpose of defining, for pharmacists, what is involved in a drug regimen review. Appendix N was updated in March of 1985 and again in September 1990. Appendix P, which contains extensive psychopharmacological drug therapy guidelines, was written in

September 1989 as part of the OBRA 1987 initiatives. These guidelines were updated in April of 1992, and again in June of 1995. In short, consultant pharmacists have extensive government guidance as to what is expected of the drug regimen review.

We would be willing to more vigorously pursue enforcement of positive resident "outcomes" which would require the pharmacist's input in achieving. For example: falls, pressure sores, and urinary incontinence can be exacerbated by psychopharmacological, cardiovascular, and other drug therapy. The pharmacist can be helpful to the nurse and physician in minimizing risk to the resident, which would be a better use of resources than investing time in further Federal regulation of the drug regimen review.

OIG Recommendation #4

HCFA should require NHs to provide ongoing, in-service training for personal care staff (nurse aides) on how to recognize behavioral signals and symptoms of contraindications, adverse reactions, or inappropriate responses to medications.

HCFA Response

We concur. However, we believe our current regulations are adequate to cover this type of course material. It is important for care givers to recognize these behavioral signs. 42 CFR section 483.152(b)(2)(i) states that the curriculum of the nurse aide training program must include taking and recording vital signs, and 42 CFR section 483.152(b)(2)(iv) requires the training program to include recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor. While these requirements do not relate specifically to possible contraindications, adverse reactions, or inappropriate responses to medications, we do not believe the nurse aides need to be able to identify the probable causes for the changes they observe. Rather, they need to recognize the changes and report them, promptly, to someone who is trained to intervene clinically. Therefore, we do not believe any related changes to our regulations or accompanying guidelines are necessary.

OIG Recommendation #5

HCFA should explore the feasibility of requiring NFs to maintain all records pertinent to a patient's care in one location in the NF.

HCFA Response

We concur and will explore the feasibility of the above recommendation.

Technical Comments

Page 12 - We note that of the problems and concerns found by the independent pharmacists (called contract pharmacists in the report), 20 percent were not identified by the facility's contract pharmacist. Among the contract pharmacists' concerns were the following:

- o lack of monitoring (drug therapy) for efficacy
- o drugs which were clearly inappropriate for use by elderly individuals
- o inappropriate method of administration, i.e., crushing of sustained action drugs
- o medications inappropriate for diagnosis
- o medications being received on schedule when a duplicate order was available
(Note: Duplicate dispensing may be one reason for high drug expenditures in Texas.)
- o some medications not having orders
- o providing medications for which the patient had allergies
- o medication being ordered for dosages other than those the patient received
(Note: These are probably medication errors.)

Also, we are interested in two questions in the context of the above findings: To what degree has the Texas state survey agency identified these problems in the last regular survey, and if the Texas state agency did identify these problems, what remedy did it prescribe?



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

TO: June Gibbs Brown
Inspector General

FROM: David F. Garrison *Jeff Merloant/for*
Principal Deputy Assistant Secretary
for Planning and Evaluation

SUBJECT: OIG Draft Report: "Prescription Drug Use in Nursing Facilities: An Inside View
By Consultant Pharmacists" --- **Concur with Comment**

We have reviewed the draft OIG report entitled "Prescription Drug Use in Nursing Facilities: An Inside View By Consultant Pharmacists" and concur with the following comments on this report.

I appreciate the OIG's findings that some pharmacists are having difficulty carrying out their responsibilities to assure accurate and adequate administration of prescription drugs in nursing facilities. Heartening, however, is the information included in this report that pharmacists contracted by the OIG for this study report that nursing homes are complying with the required medication reviews for nursing home residents. Particularly encouraging were the cooperative relationships that many pharmacists reported having with physicians, nurses, and administrators in these facilities. I believe that the information presented in this report underscores the effectiveness of the pharmacists' reviews -- precisely the result sought by enacting the OBRA '87 provisions. As the IG notes, there is still room for improvement.

Executive Summary. The body of the report correctly highlights that it is physicians who determine what is appropriate drug use for nursing home patients. However, the Executive Summary only references this critical role when recommending that pharmacists inform physicians of their medication concerns. We recommend the Executive Summary emphasize that prescribing and monitoring medications is the responsibility of the nursing home resident's physician and that many of the problems and concerns raised in this report are not the result of poor nursing home practices.

Recommendations. Among the "opportunities for improvement" suggested by the OIG are the recommendations that Appendix N of the Survey and Certification protocol be reviewed and updated, and a list of inappropriate drugs for the elderly be developed. We agree. We understand that there are several provisions in Appendix N that are no longer current and that recent advances in drug therapy for the elderly have identified several drugs that should never (or with rare exception) be used by the elderly. We recommend HCFA implement these recommendations.

Another recommendation advanced by the OIG is, “[a]s part of the on-going training of personal care staff (nurse aides), pharmacists should provide in-service training on the recognition of signals and possible symptoms of contraindications, adverse reactions, or inappropriate responses to medications.” We believe that such training would be highly desirable. We recommend HCFA consider modifying the nurse aide training program to include training on recognizing symptoms of contraindications, adverse reactions, and inappropriate responses to medications. In addition, we recommend HCFA explore whether there are cost-effective alternatives to pharmacists providing this training.

Technical and Other Comments. On a more technical note, we recommend the report clarify that the OBRA ‘87 legislative changes and subsequent regulations apply to Medicare skilled nursing facilities as well as Medicaid NFs. Similarly, we note the report indicates that “nursing facilities” were the facilities that were the subject of the pharmacists’ responses (as opposed to Medicare SNFs or dually-certified facilities). In addition, the findings and recommendations are described in terms of “nursing homes” and “nursing facilities.” We recommend clarifying the types of facilities that were the subject of this report.

As written, the report incorrectly implies that the OBRA ‘90 drug provisions are applicable to nursing homes. We recommend that the scope of these provisions be clarified. Alternatively, this discussion could be eliminated from the report.

The report states, “. . . from 1-6 percent of the consultant pharmacists say these four drug categories are inappropriately prescribed by most or all physicians . . .” (p. 11). This statement is inconsistent with the percentages reflected in Table 2. We recommend the table and the statement be reconciled.

Finally, we recommend the OIG identify any next steps that should be pursued as a result of this study. For example, your office may want to consider administering a similar questionnaire to nursing home physicians and nurses to obtain their perspectives on the effectiveness of pharmacists’ drug regimen reviews. In addition, you may wish to recommend additional research that HCFA or ASPE should consider to further our understanding in this area.

APPENDIX E

Comments by External Organizations About Inspection Draft Reports



AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

September 29, 1997

June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health and Human Services
Washington, DC 20201

RE: Draft reports - prescription drug use in nursing homes

Dear Ms. Brown:

The American Society of Consultant Pharmacists is pleased to comment on the draft inspection reports related to prescription drug use in nursing homes. ASCP is the national professional association representing more than 6,300 pharmacists who provide medication distribution and consultant services to manage and improve drug therapy outcomes of individuals residing in long-term care environments. ASCP members serve the full spectrum of long term care settings, including nursing homes, subacute care and assisted living facilities, psychiatric hospitals, facilities for the mentally retarded, correctional institutions, hospice, and home care.

We have reviewed each of the three draft reports and our comments are shown below.

ASCP's Overall Observations

1. Medications that are generally considered inappropriate for use in the elderly are referred to in the draft reports as "contraindicated." However, this is not the correct term to use for these medications. In some specific situations, the use of one of these medications in the elderly could be justified. ASCP suggests using the term "potentially inappropriate" instead of "contraindicated."
2. Parts 1 and 3 of this three part report focus on medication use and consultant pharmacy practice in Texas nursing facilities. It should be noted that Texas may not be representative of the rest of the nation with regard to long-term care pharmacy practice. One significant difference is that Texas has

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strongly emphasized the rights of individual residents to choose their own pharmacy provider, over the rights of the nursing facility. As a result, it is common for Texas nursing facilities to be served by five, ten or more pharmacy providers, each with only a few patients.

In this environment, where pharmacy providers serve only a few nursing facility patients, it is difficult for dispensing pharmacists to have expertise in geriatric pharmacotherapy and knowledge of nursing facility regulations. As a result, the task of the consultant pharmacist is made more difficult. In states where nursing facilities are served by one or two primary pharmacy providers, many medication problems are detected and corrected at the time of dispensing. This is referred to as prospective drug regimen review, and is an important complement to the retrospective drug regimen review performed by the consultant pharmacist.

ASCP recognizes the need for expanded knowledge of geriatric pharmacotherapy by both physicians and pharmacists. In order to recognize those pharmacists who have developed this expertise, and to encourage other pharmacists to develop expertise, ASCP created an independent commission to certify pharmacists in geriatric pharmacy practice. The first certification examination in geriatric pharmacy practice will be administered by the Commission for Certification in Geriatric Pharmacy on November 12, 1997.

ASCP has also developed a Statement on Pharmaceutical Care, which is designed to assist our members in improving drug therapy outcomes for their patients.

An Introduction Based on Texas

3. ASCP's Overall Observations

The first report combines information about appropriateness of drug use (e.g., medicines not generally considered appropriate for use in the elderly) and cost of medicines for nursing home residents. These are two separate issues. ASCP suggests presenting this information in two separate sections to highlight the difference.

Just because the cost of a particular drug category is increasing does not mean that medication use in this category is inappropriate. Newer (and more expensive) medications often have fewer side effects, especially in the frail elderly, and are more effective than older medications. For example, all the medications on the list of twenty drugs not considered appropriate for use in

the elderly are multisource generic products. As patients are switched off these products, they are often placed on newer, more expensive medications.

In the category of antidepressants, amitriptyline is an older tricyclic antidepressant with many adverse effects in the elderly, such as urinary retention, constipation, and dry mouth. Many nursing home residents have been placed on newer agents such as fluoxetine (Prozac) or sertraline (Zoloft). These newer agents are better tolerated by the elderly, but are more expensive.

In the antipsychotic drug category, residents are being switched from older agents such as haloperidol (Haldol) and thioridazine (Mellaril) to newer agents such as risperidone (Risperdal) and olanzapine (Zyprexa). These newer agents are less likely to produce serious side effects such as tardive dyskinesia and extrapyramidal symptoms.

In the cardiovascular category, there is increasing use of ACE inhibitors, such as enalapril (Vasotec) and lisinopril (Zestril), due to recent evidence of benefit from these agents in treatment of heart failure and prevention of renal dysfunction in diabetic patients.

4. Page i, Findings, third bullet

"In 1994 almost 20 percent, more than 16,600, of Texas' dually-entitled beneficiaries received at least one of twenty drugs considered by medical experts to be inappropriate for elderly use due to side effects or other consequences."

As noted in our introductory comments, prospective drug regimen review can be an effective means of preventing or correcting drug-related problems. As an example of this, one large long-term care pharmacy provider collected data in 1997 on 12,000 nursing facility residents across numerous states and found that only 12.9% of residents were receiving a medication on the list of twenty drugs identified in the OIG report as not appropriate for the elderly. Of these medication orders, 67% were for propoxyphene.

Increasingly, long-term care pharmacy providers are using tools such as formularies, or preferred drug lists, and therapeutic interchange as part of the prospective drug regimen review process. When properly applied, these tools can enhance efforts to improve drug therapy outcomes in nursing facility residents. Please see the attached ASCP Statement on Formularies in Nursing Facilities, ASCP Guidelines for the Development of Formulary Systems in Nursing Facilities, and ASCP Guidelines for Implementing Therapeutic Interchange in Long-Term Care.

5. Page iii, third recommendation

"Further study should be undertaken, examining data about resident conditions, types of specialized care and other facility-specific characteristics along with drug expenditure and usage data, to better understand the factors contributing to the wide differences between nursing facilities in the costs of prescription drugs used by residents."

ASCP strongly agrees with this recommendation. Because of the planned implementation of the Prospective Payment System (PPS) for nursing facilities in 1998, more research is essential to explore the reasons for these variations in costs. ASCP suggests including this recommendation in the comprehensive list of recommendations at the conclusion of the third report.

An Inside View by Consultant Pharmacists

6. Page ii, "Shortcomings of Medication Reviews"

ASCP suggests changing the title of this section to "Obstacles to Adequate Medication Reviews." The current title implies that inadequate reviews are the fault of the consultant pharmacist. In fact, the material presented in this section is primarily focused on factors that are beyond the control of the consultant pharmacist.

7. Page ii, fifth paragraph

"Pharmacists conduct some reviews without consulting important medical records and without having patients' diagnoses or laboratory reports."

The explanatory information makes clear that this information is frequently unavailable for review. ASCP suggests changing this wording to "Pharmacists conduct some reviews without access to important medical records, including patients' diagnoses and laboratory reports."

8. Page ii, sixth paragraph

"More than half of the reviews do not consider the resident's assessment (65 percent) or plan of care (56 percent)."

ASCP recommends that consultant pharmacists participate in the assessment and care planning process, and use these documents to facilitate the drug

regimen review. Please see the attached ASCP Statement on the Role of the Consultant Pharmacist in Resident Assessment and Care Planning.

9. Page iii, item 3 under "Informing and Documenting"

"Explore the feasibility of requiring nursing facilities to maintain all records pertinent to a patient's care in one location in the nursing facility."

ASCP agrees with this suggestion. However, there may be a few appropriate exceptions to this requirement. For example, the current Medication Administration Records (MARs) for all patients are commonly kept in a notebook with the medication cart for convenience in distributing medications to the residents. ASCP suggests that the OIG report include a list of pertinent patient records that should be kept in one location in the facility.

10. Page iii, "State and Federal Survey and Certification," number 1

"To enhance both surveys (Federal or State) of medication usage and monthly drug regimen reviews by consultant pharmacists, HCFA should review and update Appendix N of the Survey/Certification protocol and any related medication policy and procedures."

ASCP agrees that Appendix N is obsolete, and we suggest that Appendix N be deleted. In its present form, these survey indicators are actually counterproductive. What often happens is that surveyors, and even some consultant pharmacists, become narrowly focused on these indicators and miss other significant findings that would be more important.

ASCP is planning to coordinate development of a new set of indicators for conducting drug regimen reviews. These indicators will include the list of twenty medications considered inappropriate for use in the elderly. We will begin with a literature search and seek input and consensus from a broad group of consultant pharmacists, geriatric pharmacotherapists, physicians and others. These indicators will be updated periodically, and can be used by consultant pharmacists, surveyors, and others to evaluate appropriateness of drug therapy. ASCP will forward a copy of our new drug regimen review indicators to HCFA upon completion, no later than July, 1998.

11. Page iii, "Training of Aides"

"As part of the on-going training of personal care staff (nurse aides), pharmacists should provide in-service training on the recognition of signals"

and possible symptoms of contraindications, adverse reactions, or inappropriate responses to medications."

Nurse aides are currently required to have a minimum of twelve hours of inservice training per year, according to tag F497 of the interpretive guidelines. ASCP agrees with the recommendation for specific training for nurse aides regarding identification of medication side effects. ASCP suggests that a requirement for four hours per year (or one hour per quarter) of training related to detection of medication side effects be recommended for nurse aides.

12. Page 17, fifth paragraph

"It is interesting to note that fully 91 percent of the consultant pharmacists believe reusing medications would yield Federal and State savings (the primary exceptions are controlled drugs having Federal or State regulations that require destruction or medications in liquid form or vials contaminated by prior use). Even though some pharmacists indicated the savings may be offset by many potential administrative costs, 54 percent of the consultant pharmacists say unused, properly packaged medications could be returned to the vendor pharmacy to redispense for use by others."

The issue of return and reuse of medications by nursing facilities is complex. ASCP has developed a position statement which explores the various facets of this issue. Please see the attached ASCP Statement on Return and Reuse of Medications in Long-Term Care Facilities.

A Pharmaceutical Review of Selected Texas Patients

13. Page ii, first paragraph

"22 percent of patients were receiving, without a prescription in their records, drugs for which prescriptions are generally required. Further, 23 percent of the patients were prescribed medications for which the records showed no orders or receipts to indicate the patient actually received the medication."

This is a high proportion of such orders, and these results are inconsistent with the findings in Part II of this report, which showed that 83% of consultant pharmacists in the national survey rarely or never found a medication order not on the MAR. The remainder of the respondents found this problem "sometimes." Ninety-three percent of consultant pharmacists rarely or never find a medication listed on the MAR without an order.

14. Page ii, last paragraph

"The contract pharmacists identified medication problems or concerns for 20 percent of the patients which had not been identified by the nursing home consultant pharmacists' reviews."

It would be more accurate to say "The contract pharmacists identified medication problems or concerns in 20 percent of the patients where there was no documentation that these problems had been identified by the nursing home consultant pharmacists' reviews." Elsewhere in the OIG report, it is noted that consultant pharmacists in Texas frequently provide some of their findings to the facility in verbal reports or in documents that are not a part of their official report.

15. Page iii, "Recommendations"

In the final list of recommendations, please include the third recommendation from the first report:

"Further study should be undertaken, examining data about resident conditions, types of specialized care and other facility-specific characteristics along with drug expenditure and usage data, to better understand the factors contributing to the wide differences between nursing facilities in the costs of prescription drugs used by residents."

16. Page iii, "Recommendations"

ASCP suggests adding a recommendation that HCFA require consultant pharmacist recommendations to be made a part of the resident's clinical record. This recommendation is supported by findings from the national survey of consultant pharmacists (see Table 4 and discussion, page 16 of full report). Consultant pharmacists document their findings and recommendations in the clinical record only about one-third of the time. This lack of documentation in the clinical record decreases the ability of the consultant pharmacist to communicate significant information to the interdisciplinary team and nursing facility staff.

ASCP has long supported the documentation of consultant pharmacist findings and recommendations in the clinical record. See the attached ASCP Guidelines for Documenting Consultant Pharmacists' Activities in the Medical Record.

June Gibbs Brown
Sept. 29, 1997
Page 8

The American Society of Consultant Pharmacists is pleased to provide these comments on the draft report and we hope that these comments will be useful in your review and preparation of the final version of this report. If you have any questions about our comments, or if additional information is needed, please contact Thomas Clark, ASCP Director of Professional Affairs, at 703-739-1316, x123.

Sincerely,



R. Timothy Webster
Executive Director

enc.: ASCP Statement on Pharmaceutical Care

ASCP Statement on Formularies in Nursing Facilities

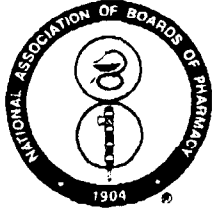
ASCP Guidelines for the Development of Formulary
Systems in Nursing Facilities

ASCP Guidelines for Implementing Therapeutic
Interchange in Long-Term Care

ASCP Statement on the Role of the Consultant
Pharmacist in Resident Assessment and Care Planning

ASCP Statement on Return and Reuse of Medications in
Long-Term Care Facilities

ASCP Guidelines for Documenting Consultant
Pharmacists' Activities in the Medical Record



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October 1, 1997

June Gibbs Brown
Inspector General
Department of Health & Human Services
Office of Inspector General
Washington, DC 20201

Dear Ms. Brown:

Thank you for the opportunity to comment on the draft inspection reports describing the results of the inspections of the issues related to prescription drug use in nursing homes.

We concur with the general findings of the reports calling for strengthening medication reviews, improving medication prescribing, administration, and monitoring practices in nursing homes. We strongly support increased use of the pharmacist in the medication review and patient care processes and access to critical patient data.

If we can be of further assistance, please do not hesitate to contact me.

Sincerely,

Carmen A. Catizone, MS, RPh
Executive Director/Secretary

CC/mwg

cc: NABP Executive Committee
Executive Officers - State Boards of Pharmacy



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October 2, 1997

June Gibbs Brown
Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W., Room 5657
Washington, DC 20201

Dear Ms. Gibbs:

The American Health Care Association (AHCA) is pleased to respond to your request for review and submission of comments on the draft inspection reports regarding issues related to prescription drug use in nursing facilities. Our comments are incorporated into this letter.

We have reviewed all three reports: *An Inside View by Consultant Pharmacists*; *An Introduction Based on Texas*; and *A Pharmaceutical Review of Selected Texas Patients*. Although our comments reference primarily the national document, *An Inside View by Consultant Pharmacists*, they are applicable to relevant areas of the Texas-related drafts. AHCA's Texas state affiliate member, the Texas Health Care Association, has also reviewed the reports and provided comments to us. Those comments are incorporated into our letter.

The American Health Care Association is a federation of 50 state health care organizations, together representing more than 11,000 non-profit and for-profit assisted living, nursing facility, and subacute care providers that care for one million elderly and disabled individuals nationally. To be Medicare and Medicaid certified, nursing facilities must be in substantial compliance with all requirements of participation at 42 CFR 483 Subpart B. These requirements include regulations governing unnecessary drugs, antipsychotic drugs, medication errors and pharmacy services, including those related to consultant pharmacists and drug regimen review.

Our comments address four key areas. They are not necessarily all-inclusive but are provided to illustrate the problems we found in the draft document discussion and recommendations.

1. Based on some of the vague descriptions of certain findings, it appears that the survey instrument which was used for obtaining information from consultant

The American Health Care Association is a federation of 51 affiliated associations, representing 11,000 non-profit and for-profit nursing facility, residential care and subacute providers nationally.

pharmacists asked broad and sometimes vague questions. Nevertheless, on the basis of responses to these broad questions, the Office of Inspector General is drawing specific conclusions and making extensive recommendations.

- Terms such as “concerns” and “inappropriate” are used in several significant areas of the text. These are broad terms which need to be broken down into specifics to limit variations in their interpretations. The concerns should be specifically described. For example, since *inappropriate* can be over-use, under-use, wrong drug for condition, or other factors, it should be specifically identified, and the percentage of occurrence of that descriptor provided. With more specific terms, the meaning of some of the findings would be clearer, and the relevance of some of the solutions to the reported problems would be more apparent. To assist the reader in understanding the problems and recommendations, we also recommend that a copy of the survey instrument be included in the final report.

2. The reports raise valid concerns about physicians’ prescribing practices, lack of knowledge or training regarding appropriate medications for the elderly, and unresponsiveness to consultant pharmacists’ recommendations. However, our reviews found that several recommendations which are made in the drafts either do not address these issues or they are targeted toward areas which will not solve the problems. They also place the burden of correction on the nursing facility, expecting facility’s administration or nursing staff to manage a process over which they do not have complete control.

- Page i of the Executive Summary of the *Inside View* draft contains this statement: “Pharmacists have serious concerns about prescribing practices for antipsychotics, anxiolytics, sedatives/hypnotics, antidepressants, and other drugs.”
- The opening paragraph on page two of the *Inside View* draft states: “It should be noted that regardless of any reported concerns by the consultant pharmacist, it is the physician’s legal responsibility to order medication changes, not the director of nursing.”
- Page 9 of the *Inside View* draft states: “Many of the consultant pharmacists (40 percent) assess the extent of cooperation from residents’ personal physicians as only fair or poor. Consultant pharmacists are disturbed that some physicians do not take their concerns seriously or act promptly on their recommendations...” It goes on to state that 63 percent of respondents report that physicians rarely or only sometimes seriously consider their recommendations. Page 9 also states: “By contrast, 99 percent of the consultant pharmacists say nurses seriously consider their concerns most to all the time.”

In spite of the above-noted statements, the draft recommendation which addresses these issues is directed at the nursing facility, as noted on page 20 of the *Inside View*: “State

and Federal survey and certification programs could include process focused reviews of pharmacists' recommendations and subsequent actions by appropriate medical and nursing personnel as part of their on-going surveys." The AHCA believes that this recommendation would penalize nursing facilities for physicians' prescribing practices and lack of responsiveness to the consultant pharmacists' recommendations, even if facilities have attempted, without success, to "educate" the physician about federal long term care regulations. This recommendation also contradicts the Health Care Financing Administration's emphasis on resident "outcome oriented" survey procedures for nursing facilities.

3. The reports contain internal inconsistencies. For example, the draft indicates that consultant pharmacists' responses to the survey show serious shortcomings in the quality and thoroughness of the pharmacists' drug regimen reviews. The draft further states that pharmacists conduct some reviews without consulting important medical records and without having patients' diagnoses or laboratory reports. Nevertheless, the consultant pharmacists responding to the OIG's survey draw conclusions about the "appropriateness" of residents' medications.

- Page ii of the draft *Inside View* contains these statements: "Pharmacists conduct some reviews without consulting important medical records and without having patients' diagnoses or laboratory reports. Many pharmacists have no contact with patients or their families or with nurse aides in their conduct of drug regimen reviews."

In spite of these significant findings, the draft emphasizes consultant pharmacists' conclusions and concerns. These responses should raise questions to the reader about how the pharmacists arrived at these conclusions without thorough knowledge of the resident's assessments, care plans, and the rationale for the use of a particular medication or dosage. For example, the chart on page 12 of the draft illustrates pharmacists' "concerns." The reader should ask how the pharmacists would know about such issues as overutilization of drugs, use of antipsychotics without a diagnosis, or use of contraindicated drugs for patients' existing diagnosis or disease given their admissions that they conduct their reviews without consulting important medical records or having the residents' diagnoses.

4. The drafts report that consultant pharmacists have serious concerns about the use of prescription drugs in nursing facilities, and the OIG suggests that legislative and regulatory intentions related to the quality of these services are not being fully realized. However, according to Health Care Financing Administration data, the rates of nursing facilities' noncompliance with key requirements of participation governing quality of care aspects of prescription drug use and the administration of pharmacy services, including those of consultant pharmacists, are not as high as the reports suggest.

- In the OIG survey, consultant pharmacists reported that, in general, nursing facilities and consultant pharmacists are complying with the law and regulations related to *medication reviews* of nursing home residents. However, the "concerns" that consultant pharmacists report in the OIG survey suggest that nursing facilities are not complying with many other federal requirements related to prescription drug use. A review of the data resulting from inspections of nursing facilities' compliance with these requirements does not support all of these concerns. For example, page 12 contains a chart which shows the percentage of consultant pharmacists who reported that they are "sometimes or often" concerned about: prolonged use of sleeping medicines (67%); overutilization of drugs (62%); use of "as needed" drugs for too long (61%); use of antipsychotics without a diagnosis (45%); and use of contraindicated drugs for a patient's existing diagnosis or disease (26%). The national rates of noncompliance cited at federal regulations related to these areas for 10,692 surveys of nursing facilities between July, 1996 and April, 1997 were:
 - 42 CFR 483.25(l)(1) -- Unnecessary drugs (in excessive dose; for excessive duration; without adequate indications for use; in the presence of adverse reactions; or a combination of the preceding) -- Noncompliance rate: 9.9 percent.
 - 42 CFR 483.25(l)(2)(i) -- If antipsychotic drugs were not previously used, they are not used unless necessary to treat a specific diagnosed and documented condition -- Noncompliance rate: 1.2 percent.
 - 42 CFR 483.25(l)(2)(ii) -- Residents who use antipsychotic drugs receive gradual dose reductions, behavioral interventions, unless clinically contraindicated -- Noncompliance rate: 1.2 percent.
 - 42 CFR 483.25(m)(1) -- The facility ensures that it is free of medication error rates of five percent or greater -- Noncompliance rate: 4.8
 - 42 CFR 483.25(m)(2) -- The facility ensures that residents are free of any significant medication errors -- Noncompliance rate: 2.3 percent
- The facilities surveyed during the above-noted time period were found to have national compliance rates of 0.8, 1.8, and 1.2, respectively, for the federal requirements at 42 CFR 483.60, including those governing drug regimen review, reporting irregularities to the attending physician and director of nursing, and acting on reports.

In addition, please note the following general comments.

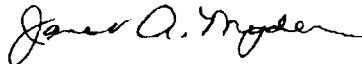
- The finding that a 20 percent increase in drug costs has occurred in a short period of time may not be unusual. Most new and more effective products that have come on

the market in the last 10 years are expensive. Their average cost is \$1.00 to \$1.50 per dose. If new, more effective drugs are now available, why should they not be used for nursing facility residents in place of the 10 to 20-year-old drug therapies? The availability of these drugs, too, is an important factor in delivering quality of care.

- Conducting drug regimen reviews on a routine basis and/or conducting reviews for the OIG's research without physically being present in the nursing facility or seeing residents produces questionable results. This practice may explain some of the pharmacists' concerns about prescription drug use in nursing facilities. If the consultant pharmacist is actually in the facility, the likelihood is increased that needed information will be obtained with the help of facility staff. Therefore, we recommend that further research be conducted before any conclusions are reached regarding the survey of pharmacists.
- We recommend that the final reports note that many of the concerns such as proper monitoring and physician prescribing practices for the elderly which are identified in these drafts are not limited to elderly individuals in nursing facilities. They also relate to those who are at home and in hospitals.
- We recommend that health professionals and the public continue to be educated about, and further research be conducted on, the use of drugs and the elderly. In addition, it is important that consultant pharmacists' clinical orientation be increased, especially through training in geriatric pharmacology.
- We recommend removal of the recommendations that require pharmacy review notes be placed in a particular location in the facility and to promote that a common drug category list be used during drug regimen reviews and medication pass reviews. Facilities need flexibility to file their pharmacy review notes where they can best be utilized by the individual facility staff. A common drug category list is not compatible with the growing younger populations in the nation's nursing facilities, in particular with the advent of subacute care.

We would be pleased to discuss these recommendations further if needed.

Sincerely,



Janet A. Myder,
Director of Regulatory Systems

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cc: Texas Health Care Association



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October 14, 1997

The Honorable June Gibbs Brown
Office of the Inspector General
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Washington, DC 20201

Dear Ms. Brown:

Thank you very much for this opportunity to comment on the *draft* reports on prescription drug use in nursing homes: "Prescription Drug Use in Nursing Facilities: An Introduction Based on Texas, OEI - 06-96-00080"; "An Inside View by Consultant Pharmacists, OEI -06-96-0081"; and "A Pharmaceutical Review of Selected Texas Patients, OEI -06-96-00082". This letter includes our general comments on the reports and we have attached specific and technical comments, also.

AAHSA represents not-for-profit organizations dedicated to providing high-quality health care, housing and services to the nation's elderly. Our membership consists of over 5,000 not-for-profit nursing homes, continuing care retirement communities, senior housing facilities, assisted living and community-based service organizations. With our broad range of facilities and services, AAHSA serves more than one million older persons daily. We have a long history and consequently, significant experience in meeting the needs of the elderly. We recognize the important role that the Medicare and Medicaid programs have played in ensuring that the health care needs of older Americans are adequately met.

AAHSA nursing facility members are committed to providing quality health care to all their residents. Prescription drugs are an important element in the medical care of residents and the findings of the OIG studies are of great interest. Some of the findings and recommendations of the reports indicate the need for further studies and could be helpful in improving the quality of medical care given residents in nursing facilities. However, we are concerned with some of the methodologies used in the study, the limited nature of the findings and the recommendations for new program requirements that are not justified by the studies.

*Representing not-for-profit organizations dedicated to providing quality
health care, housing and services to the nation's elderly*
JAMES E. DEWHIRST, CHAIR SHELDON L. GOLDBERG, PRESIDENT
Regional Offices in Albany • Chicago • Denver • Orlando

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AAHSA agrees that there is room for greater understanding of the medical needs of the elderly, particularly those with chronic conditions and multiple problems, and the "appropriate" use of pharmaceutical resources available to help them. We also recognize the potential benefits that more geriatric education of physicians, pharmacists, nursing staff, residents and their families could have on patient outcomes. However, there is a great reluctance to endorse more federal regulations or requirements for nursing facilities, one of the most over-regulated industries in the country. Once specific problems and solutions can be identified, targeted education and voluntary compliance might be the most cost effective approach.

Better communications among the physicians, patients, consultant pharmacists, and nursing facilities' staffs could eliminate some of the problems highlighted by the reports. In particular, it makes sense for the medical director to be aware of any problems identified by a consultant pharmacist's monthly review. But it is also important to recognize that each of the caregiving parties has a specific role to play dictated, in part, by state professional licensure and relationships with and responsibilities to the patient. Increased requirements for selected providers and the nursing facility, the place where the parties interact, may not be the most appropriate focus. Greater understanding by and communication among all parties should be the goal.

The analysis of TX Medicaid claims for prescription drugs (OEI-06-96-00080) indicates problems because of rising program costs, but the data needs to be interpreted in a broader context, including payment methodologies. Increased use of certain more expensive drugs, such as those that treat cardiovascular disease or depression, may very well represent better patient diagnosis and care, rather than prescription misuse. OBRA '87 has mandated the provision of NF care to bring the patient to the "highest practicable physical, mental, and psycho-social well-being" and that sometimes requires expensive drug treatments. In addition, prescribing drugs for elderly patients is a complex process unique to each case. One can not infer that all the costs associated with the 20 listed drugs are unnecessary or represent dangerous or uninformed practice. In fact, the labeling of a certain list of drugs as "contraindicated" or "inappropriate" may be misleading because unique circumstances can justify their use. Nonetheless, it is helpful to check the use of certain drugs over time

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and it is encouraging to see a 20% drop in such use over the course of the study period.

AAHSA agrees with the recommendation that HCFA continue to monitor and encourage reduction of the use of certain drugs, though changes in the prospective drug utilization review programs are not thoroughly analyzed and justified. AAHSA also agrees that HCFA should focus attention and further study on the five categories raising costs and medical concerns in the NF. The last recommendation, for further study of factors (which should include patient acuity measures) affecting the wide differences among nursing facilities in the costs of prescription drugs used by residents is particularly important as a basis for understanding the situation and designing possible changes to ameliorate perceived problems.

The report on consultant pharmacists' views (OEI-06-96-00081) is impossible to interpret because of the constraints of the methodology and lack of a detailed explanation of it. The selected consultant pharmacists were asked to recall experiences in a particular facility over a 6 month period, without records and data reflecting all relevant activities and without guidance on how to define the frequency of remembered occurrences. It is an impressionistic opinion poll of views from one set of players in a complex process with legally defined roles and responsibilities, different perspectives, and debatable interpretations. Nonetheless, some of the problems indicated by the consultant pharmacists deserve closer examination, particularly those indicating communications problems—inadequate records documentation, lack of referral to the records when conducting drug reviews, lack of reporting of monthly reviews to the medical director, etc. To better understand the nature and extent of these problems and possible solutions, all parties should be involved in study design, analysis, and recommendations, including the medical directors nursing staff.

The third report (OEI-06-96-00082), based on contract pharmacists' reviews of medical records in a small, nonrandom sample of cases, highlights other potential problems that warrant further examination before major program changes are suggested for national implementation. Therefore, AAHSA supports its recommendations that HCFA monitor and encourage reduction of certain prescription medications and identify and analyze reasons for rapidly increasing costs of certain drugs. We also support the third recommendation to strengthen the effectiveness of the medication reviews through guidance to involved

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parties. Additional changes and new requirements on a national level are not justified, given the limited information in these TX studies. We agree with the need for more education and training for all involved parties, including prescribing physicians and nursing staffs concerning "appropriate" drug use for the elderly, but it is unclear how that might best be provided, where, by whom, and payment method. The last recommendation concerning the placement of all patient care records in one location within the nursing facility is premature and unjustified, since the opinion poll shows 89% of consultant pharmacists have no difficulty obtaining a patient's assessment and 97% report no problem getting the patient's plan of care.

Our specific comments and recommendations are attached. AAHSA appreciates this opportunity to comment on these draft reports and would be happy to continue the dialog as the issues are explored further within your office and HCFA and solutions are developed.

Sincerely,



Sheldon L. Goldberg
President

Enclosure

Detailed Comments of the American Association of Homes and Services for the
Aging on DHHS/OIG Reports on
Prescription Drug Use in Nursing Facilities

An Introduction Based on Texas, OEI-06-96-00080

- The 20% increase in Medicaid drug payments per beneficiary is indeed rapid and troubling, but not surprising. New drugs have become available in the 90's for many of the common ailments of the elderly, but generic versions are not yet available and they often carry a dramatically higher price tag. In some cases the new drugs produce a better health outcome with fewer side effects. Some of the higher costs can also be attributed to better diagnosis, care and patient outcomes. Also contributing to the rapid increase in payments is the rapid inflation of prescription drug costs relative to the Consumer Price Index and the other medical components of it.
- Because the study only looks at one state and does not appear to examine the Medicaid payment methodologies for prescription drugs, it is impossible to determine how much of that increase might be due to administrative rules and procedures under the control of the state's Medicaid program.
- The study found that 17% of the state's prescription drug payments were for the dually-eligible population in nursing facilities (NFs). The dually-eligible population tends to have greater medical care needs than the average Medicaid or Medicare patient. Without further analysis of the study population selected compared to the dually eligible population in the community and to other segments of the TX Medicaid population and compared to similar populations in other states, it is impossible to assess whether that proportion may be "out-of-line". Patient acuity measures would be crucial for any such analysis.
- The finding that some NF residents receive inappropriate or unnecessary drugs is of grave concern. Given the high number of prescriptions per patient, that risk becomes more dangerous. We are well aware of the health hazards and costs associated with such treatments, particularly for the elderly. Because the elderly, especially those poor and in nursing homes, tend to have multiple health problems, the prescription problems may seem more extreme. But problems of drug use are neither unique to the elderly.

nor to nursing home residents. This study has focused on a narrow segment of the population, but the problem is much more widespread. See the enclosed cartoon for a commentary on our drug-oriented society.

- There are, however, some prescription problems related particularly to the age of NF patients. The elderly body does not process drugs as efficiently as it did when it was younger and it is more sensitive to the effects of many drugs. For those reasons, among others, there are certainly some drugs and some treatment regimens that should generally not be recommended for elderly patients. However, it is important to be cautious about labeling any list of such drugs as "inappropriate" or "contraindicated". Those terms have specific medical meaning. Appropriate use of a drug can be a debatable matter of judgment. The list of 20 drugs used in the study was constructed by a small group of experts using Delphi methods and was controversial at the time it was published. But more importantly, it must be recognized that, for some cases, it could be appropriate and necessary to use one of the drugs on the list. Based on a physician's clinical knowledge of a particular patient, the doctor could knowingly choose one of the proscribed drugs as the best option in the given circumstances. (Such use could appropriately trigger a discussion or comment from the consultant pharmacist during the monthly review, to determine whether or not it were, in fact, an "appropriate" use.)
- Despite the concerns expressed above about the drug list and how it is labeled, we are encouraged by the reduced percentage of beneficiaries receiving drugs from the list over the time period of the study. While the study notes that the percentage "shifted downward slightly" from 1992 to the first half of 1995, it is actually a 20% reduction in the rate. In part, that may reflect the growing impact of OBRA '87. In part, it may reflect the time lag frequently noted for scientific literature to have an impact on daily medical practice.
- The study shows a need for more education about drug use for the elderly that includes physicians, their patients and all caregivers, regardless of setting. Particular attention could be targeted on the five drug categories that represent rapidly growing costs to the TX Medicaid program and, within those categories, focus should be on drugs presenting the greatest risks to elderly patients. The costs of such education and who pays them need to be considered in any policy recommendations.

- On page ii, some of the findings about the 5 drug categories and gastrointestinal preparations make comparisons to "all Medicaid prescription drug payments" and it is unclear whether that refers to just the payments for the study population or the total Medicaid program.
- The finding that gastrointestinal drugs average nearly \$385 annually per beneficiary would mean \$1.05 per day not \$1.50.
- The finding that average prescription drug payments per beneficiary varied so widely among NFs may reflect, in part, the variations in practice patterns that are found throughout medical practice. However, it calls for further analysis that takes into account average case mix or patient acuity, special characteristics of NFs that may be relevant, as well as an examination of the distribution of those costs and a closer look at the outliers.
- Table 6 and the discussion above it on p.9 are a bit confusing. If the facility with the lowest total drug payment averaged \$ 0.17 per (patient?) day and had at least 6 beneficiaries during 1994, the patients must have had very short stays if the total facility payment was less than \$10.00. (The bottom row of the table multiplied by 365 does not equal the top row.) Perhaps more extreme cases need to be excluded or slightly different comparisons are necessary to be clear and meaningful.
- AAHSA agrees with the recommendations in bold type on p. 10. However, AAHSA has reservations about the inclusion of NF residents in the automated prospective drug utilization review programs already in place, without some evidence that those programs are operating smoothly in each state, reviews are timely and cost effective and that they have the capacity and expertise to handle the nursing facility population. There is no discussion of this utilization review program in the reports and no justification to support the recommendation. AAHSA supports the recommendation for further study, but does not believe that the survey of consultant pharmacists provides useful insights.

An Inside View by Consultant Pharmacists, OEI-06-96-00081

- The methodology of this survey and its written report are basically flawed and would be misleading if published. The data represents personal opinions of consultant pharmacists rather than accurate reports of activities within ...

nursing facilities. It does not present a realistic picture on which to base policy considerations.

1. While the selection of pharmacists may have been random, it is not likely that the pharmacist's selection of a facility on which to base responses could have been random in any statistical sense. As noted on page 7, you can generalize the findings, "Assuming that the pharmacists did in fact randomly select the facility for which they provided information...". Without seeing the survey instructions and questionnaire, there is absolutely no basis for making that crucial assumption and putting any faith in the findings.
2. Even if the study could document a totally random selection of NFs by consultant pharmacists, the fact that their responses are based solely on personal recall of activities over a 6 month period with no documents or records for reference to improve the accuracy of their responses and no advance warning at the beginning of the 6 month period, means that the responses are merely impressionistic, not accurate reports of actual activities.
3. Many of the responses reflect the frequency of a particular action ("often, sometimes rarely, never," or "none, few, some, most, all"), but there are no definitions in the write-up or the tables in the back explaining in numerical term what those words mean. Does that mean that there were no definitions given the respondents, either? That makes the response even more impressionistic and less useful for defining any reality. What is a rare occurrence to one pharmacist may be considered a "sometimes" event by another, or both may be weighing their answer based on the number of consultant reviews they conducted (or remembered) during the time period or by the number of dually eligible involved.
4. Because the study represents only one perspective on the situation, it may identify problems and solutions that would be of dubious merit. For example, some of the consultant pharmacists cite lack of drug monitoring through lab tests. However, this issue is open to dispute. Some physicians feel that clinical and physiologic indicators are more useful, incur less pain and cost for the patient and that lab tests are necessary when there is a change in the patient's condition or treatment plan, rather than on a set calendar schedule. Regardless of the merits of the case on either side, the identification of policy problems and solutions would be enhanced by such a debate among all involved parties.

- Given the above criticisms of the study, it is hardly necessary to comment on the substance of the report. Nevertheless, it is important to point out some of the hazards with the current write-up of the report.
 1. P.8: Such general statements as, "Pharmacists believe that nursing home patients are experiencing numerous adverse medication reactions as a result of inadequate monitoring of medications..." are dangerous because they reflect personal opinion only, do not state what percent of pharmacists actually believe that, whether they think that statement applies to 100% of NF patients or some lesser amount, and draw conclusions about relationships that are not supported by data. A pharmacist would likely see cases of urinary incontinence, depression, delirium, falls and constipation among nursing facility residents as she would among a comparably aged population living in the community. These conditions occur relatively frequently in the elderly, regardless of drug regimen. There are many contributing factors. This particular study provides no basis for concluding a cause and effect relationship with drug prescribing and monitoring as the sole (or major) causative factor.
 2. P.8: The percentages following the 8 problem statements reflect the percentage of pharmacists that think the problem occurs sometimes or often, not the frequency of cases where the problem actually occurs, but that is not clear in the write-up.
 3. Throughout this report there are statements typed in bold, "...the consultant pharmacists **express concern....**", "...are also problems according to consultant pharmacists", "Pharmacists have serious concerns about...", but it is unclear what percentage of respondents reported a problem or how frequently they observed a problem. Citing the specific questions asked and the percentages of responses might help clarify these points. For some issues, it might be reasonable to expect that each and every pharmacist that observed even one Event X ought to be concerned, but other events/issues might not be that critical.
- Because AAHSA concludes that this survey has no value beyond vague impressions and opinions, we do support further, data-based study of some of the issues discussed because they do raise questions about quality of care and the need for better communications among involved parties. Also, the

study ought to reflect the roles and activities of the various parties involved in the caring process as well as those of the consultant pharmacists, since there are legally defined roles, responsibilities and relationships that are involved and must be considered to get a full perspective of the situation.

- AAHSA does not believe this survey provides an accurate basis for consideration of policy changes or new regulatory requirements.

A Pharmaceutical Review of Selected Texas Patients, OEI-06-00082

- This report does not explain how the sample of 254 nursing home patients was selected for a desk review of their pharmaceutical regimen, and the report states that, "We do not generalize the contract pharmacists' findings to encompass all Texas nursing home patients, choosing instead to present the findings only in relation to the 254 patients reviewed." AAHSA agrees that the findings apply only to the sample of 254 residents and questions why the OIG then uses this study as the basis for making policy recommendations for regulatory and programmatic changes on a national basis for an assumed national problem. There would be significant costs nationally associated with some of the recommendations, but the costs could hardly be justified by problems identified in a nonrepresentative sample of 254 TX patients.
- This report is valuable, however, because it includes some of the cautionary language and qualifications necessary, but lacking in the previous two reports. These subtle distinctions are crucial because they highlight the uncertainties of practicing medicine and prescribing drugs for the elderly and the need for direct clinical involvement and medical judgments on a case-by-case basis in order to provide the most appropriate care for each patient. For example,
 1. P.8 "As with any medication, one should be aware that some medical situations might warrant the use of these [list of 20 drugs generally considered inappropriate for elderly patients by a panel of experts] drugs."
 2. P.8 "...contract pharmacists identified patients taking medications potentially contraindicated....." [Emphasis added.]
 3. P.9 "...the need to balance what could be inappropriate medications against the benefits of relieving or treating diseases which warrant such

usage for the enhancement or maintenance of an individual's quality of life."

4. P.9 "...records indicated other adverse effects possibly caused by medications." [Emphasis added.]

- Despite the limitations of this study, it does raise concerns and potential problems about the consultant pharmacists' reviews and their relationship with the full patient care team, including physicians, nurses and aides. AAHSA supports the essence of the first recommendations on p.13, with emphasis on further study, education and approaches to encourage better communications and better practices within the NF, rather than the imposition of new requirements. Regarding recommendation #5, there is insufficient data to support the need to maintain all patient care records in one spot in the NF. The opinion poll shows 89% of consultant pharmacists have no difficulty obtaining a patient's assessment and 97% report no problem getting the patient's plan of care.

1. Any further discussion of the issue should include a multi-disciplinary team of all care givers having any role in using the records in order to balance all needs appropriately.

2. These studies provide no justification for imposing new, national regulations— the nature of the problems are not thoroughly understood, all parties involved in the NF should be involved in the analytical process, and the costs and benefits of alternative policy options have not been analyzed.

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A national organization of
long term care physicians
committed to quality care

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October 6, 1997

Ms. June Gibbs Brown
Inspector General
Dept. of Health & Human Services
Washington, D.C. 20201

Dear Ms. Brown:

Thank you for providing the American Medical Directors Association with the three draft inspection reports describing the results of your review of issues related to prescription drug use by dual eligible residents in nursing facilities in Texas. As the major association representing physicians interested in and committed to the care of nursing facility residents, AMDA is disappointed that it had only a brief window of opportunity to respond to these documents. There is very little information to interpret in these documents, however, since they are primarily expanded executive summaries. AMDA has worked diligently with HCFA and others over the last 15-20 years to improve quality of care in nursing facilities, has provided educational opportunities for physicians interested in long term care, has developed a certification program for medical directors in long term care, and has developed clinical practice guidelines for a number of common problems encountered in the nursing home, including congestive heart failure and depression. We also offered to assist you and your staff, in the meeting on March 4, 1997, with Michael Mangano, George Grob, Thomas Roslewicz, Jack Hartwing, Judy Holz, and Debra Robinson. Despite this long history of achievement and commitment, AMDA was not asked to help at an earlier stage in this process.

While AMDA agrees that there is much to be done to assure that each individual nursing facility resident in U.S. nursing facilities receives an appropriate drug regimen, making decisions based upon Medicaid data sets, opinion polls and a sample of 254 nursing facility residents in Texas may be extremely risky. A main concern with Medicaid data is that linking drugs prescribed, impact of Medicaid formularies, validation of actual diagnoses, and the extent of involvement of various members of the health care team is difficult, if not impossible. While lack of primary data makes it difficult to discuss specifics of these documents, several broad generalizations are submitted for your consideration.

First, it is not unexpected that an increase in the use of cardiac and cardiovascular drugs would occur in the nursing facility setting. There is now good evidence that more aggressive treatment of congestive heart failure enhances quality of life and decreases episodes of acute exacerbation of congestive heart failure, thereby decreasing episodes of hospitalization. A cornerstone in the treatment of CHF is ACE inhibition, requiring a relatively expensive class of drugs. In addition, the complications associated with isolated systolic hypertension in the elderly may be reduced by more aggressive treatment of elevated pressures, thereby accounting for

an increased use in cardiac and cardiovascular drugs as well. Depression is also more aggressively identified, diagnosed, and treated in the nursing home setting. The newer and safer antidepressants are clearly also much more expensive. With regard to infections, more patients are transferred from acute hospital stays into the long term setting who require antibiotics, and, additionally, residents may be more apt to be treated for infections in the long term setting rather than be transferred to the acute hospital setting when an intercurrent infection arises.

Again, it would not seem prudent to base any major regulatory or legislative changes at this point on inspection of current Medicaid data and opinion poll of only one member of the long term care interdisciplinary team. There is a problem with the appropriate use of medications in the nursing facility setting just as there is in any setting in which the frail elderly are treated. The problem, however, needs to be clarified and solved by employing a team effort and implementing a continuous quality improvement process not by the continued merry-go-round of legislation and regulation.

AMDA suggests that you consider replicating the team to help with these issues. The team should include, in addition to physicians and consultant pharmacists, nurses, social workers, nutritionists, psychologists, speech, physical and occupational therapists, ombudsmen for long term care, and, importantly, residents and their families. Only then can data derived from other sources be interpreted in a meaningful way, and only then can the quality of care provided to dual eligible residents in nursing facilities be enhanced.

One member of the interdisciplinary team that has been omitted from drug review notice requirements is the medical director. Currently, consultant pharmacists are not required to notify the medical director of concerns or recommendations arising from drug regimen reviews. We recommend that the nursing facility medical director be required to be notified of the results of the consulting pharmacist's drug reviews. The medical director is responsible for monitoring the medical care provided in the nursing facility and is the most appropriate individual to follow up with attending physicians on the comments and concerns of consulting pharmacists. We believe that mandating such inclusion will strengthen the effectiveness of drug regimen reviews, as well as improve the quality of patient care. Our specific comments and recommendations are attached.

AMDA has demonstrated its interest in working with the Office of the Inspector General, as evidenced by our meeting on March 4, 1997, and by our invitation for a representative of your office to speak at our annual meeting in March of 1998. AMDA will be contacting your office within the next several days to request a meeting to discuss these issues more thoroughly. In the meantime, I urge you to consider these comments as you decide how to proceed with further action related to the three documents.

Sincerely,

Larry Lawborne

Larry Lawborne, MD, CMD
President

**ADDITIONAL COMMENTS OF THE AMERICAN MEDICAL DIRECTORS
ASSOCIATION ON OIG REPORTS ON PRESCRIPTION DRUG USE IN
NURSING FACILITIES**

October 6, 1997

**OIG Report - "Prescription Drug Use in Nursing Facilities: An
Introduction Based on Texas" (OEI-06-00080; May 1997)**

Background:

As noted in Dr. Lawhorne's cover letter, AMDA is extremely concerned about inappropriate use of prescription drugs that result in poor patient outcomes and hospitalization. As an organization, we endeavor to raise the standard of practice in long-term care settings by education programs that are devoted to appropriate drug use, as well as articles in our journal, Nursing Home Medicine, The Annals of Long-Term Care. We also provide instruction on appropriate drug use in our programs to certify long-term care medical directors. In addition, many of our 40 state chapters have provided educational programs on appropriate drug use in the elderly. We are well aware of the unfortunate outcomes that may result from the use of drugs that are inappropriate or not medically necessary.

We are, however, mindful that the cornerstone of nursing facility reform is individualized care planning and treatment of each individual resident. While drug guidelines are very useful, in individual circumstances physicians may prescribe drug regimens that vary from the guidelines but are, in fact, the optimal drug therapy for that individual patient. You may wish to include in your discussion of OBRA the fact that the Resident Assessment Instrument/Minimum Data Set (RAI/MDS) represents OBRA '87's focus on ensuring that every nursing facility resident's individual needs are met. Furthermore, OBRA '87 requires that nursing facilities provide services to ensure that each resident achieves his or her "highest practicable physical, mental, and psychosocial well-being." The requirements for individualized care plans as well as care and services to achieve the resident's highest practicable well being may all influence the course of drug therapy in ways that may deviate from a "cookie cutter" approach.

We appreciate the OIG's recognition that potential drug use problems are compounded in the elderly, who tend to be taking several drugs at one time. It is of great interest to us to note that the contracted consultants used for the pharmaceutical review in Texas reported reviewing records of patients with an average of three primary and three secondary diagnoses, who received an average of ten medications. Such complex interactions of medical conditions and drugs certainly require careful monitoring.

The OIG analysis seems to rely on one article's conclusions regarding prescription drugs that should not be prescribed for elderly patients (Beck, Ozlander, Rollingher, et al., "Explicit Criteria for Determining Inappropriate Medication Use in Nursing Facility

Residents." *Archives of Internal Medicine*, Vol. 151 (Sept. 1991), pp. 1825-32. It should be noted that although the drugs listed in Appendix A include many that most geriatricians would avoid in treating elderly patients, there was some controversy in the medical community about the article, particularly about the Delphi method used in reaching its conclusions. A review of comments and letters to the editor following publications of the article could provide some context for the controversy. The list of inappropriate medications in nursing facilities should be made with a broader consensus and revisited periodically.

Findings:

- Like the OIG, AMDA is concerned that prescription drug payments for dually eligible Texas nursing home residents have increased rapidly, rising by 20 percent from 1992 to 1994. The data from Texas is consistent with reports from managed care companies, hospitals, and patients. The cost of drugs has clearly risen rapidly, and many new, very expensive drugs have come on the market in the past four to five years. Concurrently, with the shared emphasis and attention on providing the highest practicable functional level and quality of life, the typical nursing facility resident is receiving much greater medical attention and treatment than in the past.
- Regarding increased drug use, as noted in Dr. Lawhorne's letter, it is not unexpected that an increase in the use of cardiac and cardiovascular drugs would occur in the nursing facility setting. There is now good evidence that more aggressive treatment of congestive heart failure (CHF) enhances quality of life and decreases episodes of acute exacerbation of congestive heart failure, thereby decreasing episodes of hospitalization. A cornerstone of CHF is ACE inhibition, requiring a relatively expensive class of drugs. In addition the complications associated with isolated systolic hypertension in the elderly may be reduced by more aggressive treatment of elevated pressures, thereby accounting for an increased use in cardiac and cardiovascular drugs as well. Depression is also being more aggressively identified, diagnosed, and treated in the nursing home setting; the newer and safer antidepressants are clearly much more expensive. With regard to infections, more patients who are transferred from acute hospital stays into the long-term care settings require antibiotics. Additionally, residents may now be more apt to be treated for infections in the long-term care setting than to be transferred to the acute hospital setting when an intercurrent infection arises. Furthermore, in light of OBRA '87's requirement to provide services to achieve the resident's highest practicable well-being, physicians would have great difficulty in limiting drug therapies for anti-infectives, cardiac drugs, and antidepressants if they are medically appropriate. The fact that a small number of drug categories account for an expanding majority of prescription drugs is also true in most areas of adult medicine, reflecting the new therapies, high demand, and high prevalence of gastrointestinal, cardiovascular, and psychiatric problems in the nursing facility population.
- The report concludes that some nursing facility residents are receiving drugs that are inappropriate or not medically necessary, raising cost and quality of care concerns. All inappropriate drug use should be condemned, but the designation of

"inappropriateness" is subject to considerable interpretation. See comments above regarding the lead article apparently relied upon to determine appropriateness.

- Regarding drug costs, we note with interest Table 5, which reflects the percent change in total beneficiaries receiving prescription drugs and total payment for five drug classifications. Clearly there is a vast discrepancy when the percent of beneficiaries receiving gastrointestinal preparations has increased 15.5%, while the cost has risen 93.5%; or when the percent of residents receiving psychotherapeutic drugs has increased nearly 10% but the cost has increased nearly 92%. The other categories of drugs show similar, although slightly less dramatic, trends. This vast increase in drug payments raises the question of what states may be doing to control the cost of these drugs.
- The draft report notes that total prescription drug payments, average payments per day, and average payments per beneficiary vary widely by Texas nursing facility. AMDA concurs with OIG on the need to further analyze variables such as size of facility, facility type, severity of illness, types and numbers of other services. We recommend specific focus on patient acuity, which we believe has increased in recent years. We note that variations have been observed in medical treatments, procedures, and prescribing throughout many areas of health care services, e.g., TURPs and hysterectomies. Ongoing efforts to understand and address this variability are highly desirable.

Recommendations:

- AMDA agrees with the recommendation that HCFA should continue to monitor and encourage reduction in the use of inappropriate or poorly effective prescription drugs in the elderly population. We also agree that at the facility level, surveyors, consultant pharmacists, and physicians should be reminded of the dangers associated with such drugs and directed to actively pursue a reduction in their use. We also concur that similar analysis of data from additional states should be undertaken to further assess the extent of the continued use of these contraindicated drugs. We do, however, recommend that a formal definition of OIG use of the terms "contraindicated" and "ineffective" be adopted, in order to facilitate uniform review. It is important to note that inappropriate and contraindicated are not synonymous terms in medicine. We also suggest that the list of inappropriate drugs should be stratified with emphasis on drugs that are the most likely "offenders" and have reasonable alternative treatments. We recommend collaboration between HCFA and professional organizations to publish information, which AMDA could publish and disseminate.
- The significant increase in drug costs is of universal interest for patients and physicians; it should be reviewed as an all-pervasive issue, not as peculiar to nursing facilities. Consideration of drug use and costs in nursing facilities alone poses the danger of creating an inferior standard of prescribing for nursing facility patients. We do appreciate the OIG's concern for increasing Medicaid costs, but an appropriate approach may be for the Medicaid agency to focus the disproportionate increase in

their costs beyond what is explained by increased use. increase in beneficiary use would seem to warrant. We do not believe it is necessary to single out certain types of drugs for review as to medical necessity. It is AMDA's position that all medications ordered should be medically necessary.

- We agree with the OIG that further study should examine data about resident conditions (particularly severity of illness, as noted above), types of specialized care and other facility-specific characteristics, along with drug usage and expenditure data, to better understand the factors contributing to variations between nursing facilities in the costs of prescription drugs by residents. We also suggest analysis of resident assessments to gain better understanding of the individual factors that may influence medication choice, and analysis of whether, in the case of questionable medication regimens, other more traditional regimens had been prescribed and then discarded as not effective in a particular patient.

Comments on OIG Report - "Prescription Drug Use in Nursing Facilities: A Pharmaceutical Review of Selected Texas Patients" (OEI-06-96-00082; May, 1997)

Background:

Omnibus Budget Reconciliation Act of 1987: This section should include a discussion of OBRA '87's focus on individualized assessments and care plan requirements, as well as its requirements to meet the resident's highest practicable well-being, as discussed above, due to the possible impact those requirements may have on drug therapy.

Omnibus Budget Reconciliation Act of 1990: The summary in the OIG report does not mention that the OBRA '90 amendments specify that the pharmacist must offer to counsel patient or their caregivers (emphasis added) on directions and precautions for preparation, administration and use; common adverse effects and therapeutic complications, proper storage, etc. We assume that for nursing facility patients, "caregivers" would refer to the nursing staff of the nursing facility.

Physicians Determine What is Appropriate for Each Patient: AMDA is pleased to see OIG recognition of the fact that it is the patient's attending physician or the facility's medical director who determine what is appropriate care, including prescribing medications to meet patients' needs.

The OIG correctly notes that OBRA 87 requires that the pharmacist report any identified irregularities to the attending physician of the patient and the director of nursing, and that these reports be acted upon. The medical director, who monitors the physician care and is in the best position to ensure that the reports are acted upon, has been left out of that information loop. There is no requirement that the medical director be informed of concerns of the consultant pharmacist.

When consultant pharmacists have decided to inform the medical director of irregularities, medical directors have not found problems with the format in which such reports are made. We feel that it would be burdensome for physicians to be required to include with their orders a medical outcome expectation for each prescribed medication. For most drugs, the expectations should be quite clear from the patient record. For example, a patient with terminal cancer who is receiving a narcotic analgesic patch for pain control will probably need medications for constipation and nausea, common side effects of the analgesic regimen. Another common example is the usual need for potassium supplementation for patients receiving loop diuretics.

Regarding notice of acceptance or rejection of consultant pharmacist's concerns, we expect that would be addressed in the notes from the next regular physician's visit to the patient. Care should be taken not to create an additional paperwork burden for medical and nursing staff in responding to those concerns.

Findings:

Quality of Care Issues:

- As noted in the report, the prevalence of signs and symptoms of various diseases and geriatric syndromes present in this population are easily confused with adverse drug reactions. It requires the diagnosis and judgment of a physician to differentiate a cause and effect relationship and advise a patient on the risk/benefit of any treatment. This entire subject should not be addressed without physician input.
- Appropriate use and monitoring of medication in a nursing facility population is and always will be important and difficult. The best process for this is as yet undiscovered. A combined effort among the interdisciplinary team, including the physician and medical director, seems ideal. This, however, requires expanded roles and funding for this work.
- Regarding findings on drugs considered inappropriate in the elderly, please refer to comments. The list of inappropriate medications in nursing facilities should be made with a broader consensus and revisited periodically.
- AMDA is concerned that findings of the contract pharmacists indicate that some patient may be experiencing unnecessary adverse medication errors as a result of inadequate monitoring of medications. In response to the finding that 23 percent of the records had no indication that required lab testing had been performed, we should observe that many carriers are increasingly reluctant to cover routine laboratory tests due to lack of evidence about the extent and frequency of the need for such tests, e.g., how often should a patient receiving loop diuretics and potassium supplements have serum potassium determinations, and would the frequency differ if the patient is on an ACE inhibitor or digoxin? A separate aspect of the lack of consensus over appropriate laboratory monitoring relates to the fact that many physicians do not agree with some guidelines for recommended monitoring, feeling that clinical and physiologic indicators are more useful, incur less pain and cost for the patient, and are

less likely to create a need for investigating possible abnormal lab results, which may be very expensive and worrisome and yet produce no real benefit to the patient.

Shortcomings of Medication Reviews:

- We note that that well-unified and organized medical records overlap between sites of service and present a major challenge in every area of health care.
- Regarding the OIG's findings that resident medication records are often incomplete, making it difficult or impossible to clearly identify or confirm potential drug regimen problems, AMDA observes that this is a complex problem. Many patients have problems that evade precise diagnosis and vague problems that fit into many categories, and those should be noted in the progress notes. In many other aspects, the OIG findings represent a systems problem that is beyond the control of either medical directors or attending physicians.

Recommendations:

- AMDA agrees that HCFA should continue to monitor and encourage reduction in the use of contraindicated prescription drugs in the elderly nursing facility population. We reiterate our request that the terms "contraindicated" and "inappropriate" be defined, in order to ensure uniform interpretation.
- AMDA agrees strongly that HCFA should identify and analyze the reasons for rapid escalation in costs and claims for certain types of drugs used in nursing facilities. While the increased use of drugs among residents may be simply the result of increased acuity of resident case mix (e.g. in the case of antiinfectives), or improvements in diagnosis and treatments (as in the case of antidepressants), and may be entirely appropriate, the escalation in drug prices seems disproportionate to the increase in drug usage, and should be reviewed. Trends in nursing facility prescription drug use should be compared with national data on prescribing and costs.
- AMDA supports the concept of strengthening the effectiveness and impact of medication reviews, and we suggest the OIG recommend that the nursing facility medical director be required to be involved in that process. The effectiveness of information provided by the consultant pharmacist would be dramatically increased if HCFA required the medical director to be notified of the consulting pharmacist's concerns. The medical director is responsible for monitoring the medical care provided by attending physicians, as well as intervening as needed on behalf of the patient or the facility's current administration. As both the medical director and a physician colleague, the medical director is in the best position to ensure that findings of the consultant pharmacist are acted upon. Our suggestion is reinforced by data in the OIG's pharmacist survey showing that cooperation between medical directors and consultant pharmacists is considered good or very good by more than 71% of respondents.
- AMDA does not agree with OIG's recommendation that HCFA should "encourage prescribing physicians to provide clinical outcome expectations for any medication

prescribed, and requiring pharmacists to monitor for these expectations." As noted above, general clinical expectations will be clear in the case of most medications. If a physician is using a drug to treat a condition other than that for which the drug is normally prescribed, it is reasonable to expect that the physician should clarify the condition that the drug is expected to treat.

- AMDA agrees with the recommendation to require nursing facilities to provide on-going, in-service training for personal care staff (CNAs) on recognizing behavioral symptoms of contraindications, adverse reactions, or inappropriate responses to medications. CNAs are the front-line of nursing home care, and their assistance in recognizing symptoms of medication problems could greatly enhance the quality of resident care. First, however, there should be increased funding for staff and continuing education efforts to enhance interactions between the physicians, pharmacists, and facility staff. It would not be prudent to train nurse aides to look for medication side effects that are hard to discern and interpret even for trained physicians and pharmacists, without a formal process and structure to ensure that physicians and pharmacists are already communicating among themselves about these issues. To train nurse aides without first ensuring that the physician-pharmacist link is working effectively would be disruptive to patient care and overall confidence in a nursing facility.
- Regarding the recommendation concerning medical records, AMDA believes that medical record organization and availability should be driven by patient care needs and not convenience. Most attending physicians have faced exactly the same issue: ready access to the entire medical record. However, we recognize that good and accessible patient care is at stake. This problem would need to be addressed by a collaborative effort of nursing facility staff, medical directors, attending physicians, and pharmacists.

Comments on OIG Report – "Prescription Drug Use in Nursing Facilities: An Inside View by Consultant Pharmacists" (OEI-06-0081)

Methodology: This study appears to be a totally subjective survey that is not based on chart review or any other evidence-based data. For that reason, we question the weight that should be given to this report. We recommend that the OIG not publish this report but rely instead on the evidence-based report by contracted pharmacist reviewers. The findings of this survey are interesting, but may be more appropriate for a pharmacists' journal than for a report by a Federal agency. Publishing this report could create a precedent that every group of health care professionals might petition the government to commission a report on how they might better fulfill their statutory responsibilities.

Findings:

Quality of Care Issues:

- The survey of pharmacists raised a number of issues regarding inappropriate prescribing practices; inadequate monitoring of medications; concerns regarding prescriptions for antidepressants; etc. Because these issues arise from a survey based

on generalized impressions and not on actual data or actual chart review, it is difficult to respond to them *meaningfully*.

- Notwithstanding the non-factual basis of the survey, we observe that respondents noted a need for greater monitoring of continued need for medications, and monitoring of potentially toxic drugs. Any focus on increased laboratory monitoring should be coordinated with Part B carriers, to ensure coverage of appropriate tests.
- We note that a number of consultant pharmacists assessed the extent of cooperation from residents' personal physicians as only fair or poor. One aspect of this feeling of non-cooperation appeared to be that consultant pharmacists were disturbed that some physicians do not take their concerns seriously or act promptly on their recommendations. Many pharmacists complained that physicians rarely or never seek their help regarding appropriate medications or proper dosages. Physicians in long-term care settings use consultant pharmacists as consultants. That is, physicians call on consultant pharmacists when physicians want additional information on medications. Most of the time, physicians do not need such consultant services. Clearly, cooperation with appropriate recommendations from consultant pharmacists is important, and the nursing facility medical director is in the best position to secure that cooperation. AMDA's conclusion seems to be borne out by Table 6, which shows that 71.4% of respondents considered the cooperation between the consulting pharmacist and medical director to be good or very good. OIG should recommend that HCFA close the feedback loop in consultant nursing facility drug reviews by mandating that the medical director not only be informed of concerns and recommendations, but that the medical director oversee the reviews by the consultant pharmacist. Such a change would allow the medical director to more effectively monitor the medical practice of attending physicians as well as coordinate resident care.

Shortcomings of Medication Reviews:

- Once again, given the anecdotal nature of this survey, it is difficult to have sufficient information on which to base comments. For example, 35% of respondents indicated that they had difficulty in obtaining the patient's diagnosis. Since the OIG report correctly observes that information on diagnosis should be in the patient's record in at least one of three places (the MDS, the patient's personal assessment, or the plan of care), it seems extremely unlikely that a diagnosis would not be found in at least one of those places. That calls into question the validity of the report, or at best, makes interpretation of its findings extremely speculative.
- More than half of respondents stated that they do not routinely review a resident's medication regimen against either the routine resident assessment or plan of care for each patient. That finding raises serious questions regarding the validity of the drug regimen review. It is difficult to understand how a valid drug review could be done without reviewing the resident assessment or plan of care.

- Some respondents voiced "strong concerns" about limitations on their professional authority to enforce OBRA provisions. Federal and State survey and certification agencies have been charged with enforcement responsibilities, not consultant pharmacists. It is extremely unrealistic for consultant pharmacist to imagine that they could or should be able to ensure a facility's or physicians' adherence to OBRA provisions, or guarantee that the nursing staff properly administer medications demonstrates a lack of comprehension of the appropriate roles of various members of the interdisciplinary team

Opportunities for Improvement

- AMDA strongly endorses the OIG's recommendation that medical directors should always be informed when pharmacists have patient medication concerns. Such notice to the medical director is not currently required by HCFA regulations. As noted above, AMDA believes that notice to the medical director would improve compliance with appropriate pharmacists recommendations.