

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PRESCRIPTION DRUG USE
IN NURSING HOMES**

Report 1

An Introduction Based on Texas



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**November 1997
OEI-06-96-00080**

EXECUTIVE SUMMARY

PURPOSE

To describe the extent and appropriateness of drug use by Medicare and Medicaid residents of Texas nursing homes.

BACKGROUND

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.

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. 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.

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 first. To assess the extent of prescription drug use for Medicare and Medicaid nursing home residents, we obtained Medicaid data for Texas for calendar years 1992 through 1994 and the first six months of 1995.¹ We report total program expenditures by year and total expenditures by drug class, offering a more detailed understanding of precisely what types of drugs are being used in nursing homes and in what volume they are being used. We also consider expenditures on drugs regulated by the OBRA 1987 or deemed inappropriate for use in elderly populations.

The second report of this series, "An Inside View by Consultant Pharmacists," presents the results of a national survey of consultant pharmacists who perform Federally-mandated monthly drug regimen reviews in nursing homes. The third report, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06--96-00082), discusses results from an independent review of drugs and medical records for a sample of Texas nursing home patients. Recommendations addressing the issues and concerns raised collectively by all three reports are located in the third and final report of this inspection.

FINDINGS

Taken together, the three reports of this inspection show that while progress has been made in improving pharmacy practices in nursing homes, some weaknesses and vulnerabilities still exist which warrant attention. Following are the findings from the first report:

Prescription drug payments for Texas Medicare and Medicaid nursing home residents have increased rapidly, rising by 20 percent from 1992 to 1994.

- The average payment per beneficiary increased 20 percent from 1992 to 1994, much faster than the one percent increase in beneficiaries receiving drugs and substantially greater than the rate of inflation for this period.
- Drug payments for this population are a significant portion of State and Federal program expenditures; more than 17 percent (\$91 million) of Texas' total prescription drug payments of \$535 million were for the Medicare and Medicaid nursing home population.

Some nursing home residents are receiving drugs which are potentially inappropriate or not medically necessary, raising cost and quality of care concerns.

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 determines what is appropriate care.

- In 1994 almost 20 percent, more than 16,600, of Texas' Medicaid and Medicare 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.
- It does appear that a slight reduction has been achieved for the twenty most frequently discussed potentially inappropriate drugs. The percentage of beneficiaries receiving at least one of the drugs has shifted downward from 21.2 percent in 1992 to 17 percent for the first half of 1995. However, the rate of resident use of contraindicated drugs remains high enough to be a continuing serious concern.

Five drug categories account for an expanding majority of total payments for prescription drugs.

- Gastrointestinal drugs, drugs for cardiovascular and cardiac care, psychotherapeutics, and anti-infective drugs combine to total more than half of Medicaid payments for prescription drugs in this population.
- Total payments for drugs in these categories increased at very high rates, ranging from 60 percent to 94 percent, between 1992 and 1994.

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 the third and final report of this inspection, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06-96-00082).

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 the third and final report of this inspection, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06-96-00082).

- More than 50 percent of Medicare and Medicaid beneficiaries received drugs from at least three of these top five categories in each of the years considered.

Gastrointestinal preparations comprise an increasing proportion of the prescription drugs used in Texas nursing facilities. Closer scrutiny of the medical necessity of these very expensive drugs appears warranted.

- Almost 47 percent of the residents in our dataset received at least one gastrointestinal drug in 1994; their total cost to Medicaid was over \$15 million. This single drug class accounted for almost 17 percent of all Medicaid prescription drug payments in that year, a substantial increase over the 1992 share of 12 percent.
- This class of drugs is one of the most expensive, with average payments per beneficiary of nearly \$385 and an average cost per day of \$1.05.
- A 1992 study suggests that at least 40 percent of nursing home residents who receive these drugs are receiving them for conditions other than those indicated in the medical literature. Therefore, curtailing unnecessary or inappropriate use of gastrointestinal drugs could result in sizeable program savings.

Total prescription drug payments, average payments per day, and average payments per beneficiary vary quite widely by Texas nursing home. The reasons for and appropriateness of these variations are unclear.

Average 1994 prescription drug payments, when arrayed by nursing home, range from a high of more than \$8 per day to as little as 17 cents per day. Total payments per beneficiary begin at just over \$5 and increase to more than \$485.

RECOMMENDATIONS

Based on the concerns raised in this report, the Health Care Financing Administration (HCFA) should work with the States and other responsible entities to understand reasons for the rapid escalation in costs and claims for certain types of drugs used in nursing homes. Specific recommendations for HCFA to consider in this endeavor are provided in our third report, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06-96-00082).

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.

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INTRODUCTION

PURPOSE

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BACKGROUND

Medicaid and Long Term Care

The Medicaid program, created in 1965 under Title XIX of the Social Security Act, represents the second largest health care expenditure for the Federal government. Funded jointly by Federal and State governments, it is designed to provide certain basic medical services, including inpatient hospital care, physician services, and nursing home care. More than 36 million people received \$90.7 billion in Federal money and another \$68.8 billion in State funds for Medicaid reimbursed services during fiscal year 1995.²

In 1995, Medicaid was the primary payment source for the personal health care for 4.4 million Americans over 65. Long term care is one of the largest and fastest growing needs of the elderly. Medicaid is the primary public program for long term care assistance for the elderly and disabled. In fiscal year 1995, of \$39 billion in program expenditures for care for this population, \$29 billion went for nursing home stays.³

Prescription Drug use in Nursing Homes

Payments for prescription drugs represent a large portion of Medicaid's expenditures for nursing homes. Estimates of the average cost per bed range from \$600 to \$1000 per year.⁴ 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. 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. But, health care costs associated with inappropriate use of prescription drugs add to these estimates.

Potential Problems and Costs

Several recent studies suggest that inappropriate use of prescription drugs by the elderly is a potentially serious health problem and could be adding hundreds of millions of dollars each year in unnecessary drug and hospitalization costs. The inappropriate use of these drugs can take a number of the following forms:

- drug-age contraindication,
- drug-allergy contraindication,
- drug-disease contraindication,

- incorrect drug dosage,
- incorrect duration of drug therapy, and
- less effective drug therapy.

While approximately 3 percent of all hospital admissions are caused by adverse drug reactions, the percentage is much higher for the elderly. One study estimated the percentage of hospitalizations of elderly patients due to adverse drug reactions to be as high as 17 percent, almost six times greater than for the general population.⁵ The Food and Drug Administration (FDA) estimates that the annual cost of hospitalizations due to such inappropriate drug use is 20 billion dollars.⁶ Much of this cost is in the elderly population and a large portion of it is borne by government health care programs, including Medicare and Medicaid.

Not only do the elderly use more prescription drugs than any other age population, they also tend to be taking several drugs at once, increasing the probability of adverse drug reactions. The elderly also tend to eliminate these drugs from their system less efficiently due to decreased bodily functions. Studies also suggest more subtle effects of inappropriate drug use, such as loss of cognitive or physical function and the potential for an increased risk of falls among the elderly. Researchers have concluded that a number of prescription drugs used for the general population should not be prescribed for elderly patients (See Appendix A). Frequently, other equally effective drugs which present fewer risks are recommended.^{7,8}

Regulation and Control of Prescription Drug Use in Nursing Homes

As part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), Congress required regulation of the use of certain drugs in nursing homes. On October 1, 1990, the Health Care Financing Administration (HCFA) implemented regulations which hold nursing homes accountable for monitoring drug use.⁹

Additionally, physicians must now justify the use of antipsychotic drugs based on specific diagnoses and observe specific parameters within which these drugs may be used. While recent studies indicate that the OBRA 1987 regulations may have had a positive effect on reducing antipsychotic drug use in this population, there is some evidence of continuing problems of inappropriate prescriptions, multiple prescriptions, and possible drug-drug interactions. For example, a July 1995 study of 21,884 nursing home residents found that 12 percent of residents in the study were prescribed one or more of 10 nonpsychotropic medications that are considered inappropriate for use in the elderly. Thirty-one percent of those residents were receiving more than seven prescription drugs, and 19 percent of this group had prescriptions for at least one inappropriate medication.¹⁰

METHODOLOGY

This report documents prescription drug expenditures and identifies the types of drugs being used in Texas nursing homes. As part of preinspection, we reviewed 1) current literature related to prescription drug use by the elderly and 2) Medicare and Medicaid policies

associated with payment and monitoring drug use. To assess the extent of prescription drug use by Medicare and Medicaid residents, we obtained Medicaid data for Texas nursing home residents eligible for Medicare and Medicaid for calendar years 1992-94 and the first six months of 1995. The selection of Texas was purposive 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 (see description below), 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.

This inspection provides insight into several issues related to prescription drug use in nursing homes. First, we report total program expenditures by year and total expenditures by drug class, offering a more detailed understanding of precisely what types of drugs are being used in nursing homes and in what volume they are being used. We also consider expenditures on drugs regulated by OBRA or deemed inappropriate for use in elderly populations.

For ease of analysis and understanding we have compressed the several thousand different drugs in our study into 32 general categories. Drugs are combined based on therapeutic function and pharmacological makeup. For example, the category for which Federal programs paid the most in 1994, gastrointestinal preparations, include such types of drugs as those intended to treat ulcers, limit the secretion of certain gastrointestinal fluids, or to treat gastrointestinal reflux. Some of the most common brand names in this category include *Zantac* and *Pepcid*. Other categories include: cardiac, psychotherapeutic, cardiovascular and antiinfective drugs. A complete list of the categories and the types of drugs each contains appears in Appendix B. Although we collected and analyzed Texas prescription drug data for the years 1992 through the first six months of 1995, much of the discussion in this report is focused on the most current year for which we have complete data, 1994, with comparisons to the other years where appropriate. Because of the difficulty in estimating the nursing home population for the full year of 1995, no attempt was made to project these figures beyond June 30, 1995.

This is the first in a series of three reports detailing our inspection of issues related to prescription drug use in nursing facilities. The second report, "An Inside View by consultant Pharmacists" presents the results of a national survey of consultant pharmacists who perform Federally-mandated monthly drug regimen reviews in nursing homes. The final report, "A Pharmaceutical Review and Inspection Recommendations" presents the findings from a pharmaceutical review of the records of a number of Texas nursing home residents and the collective recommendations of all three reports.

This inspection was conducted as a part of Operation Restore Trust (ORT). The initiative, focused in five States (California, Florida, Illinois, New York, and Texas), involves multi-disciplinary teams of State and Federal personnel seeking to reduce fraud, waste, and abuse in nursing homes and home health agencies, and by durable medical equipment suppliers. This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Prescription drug payments for Texas Medicare and Medicaid nursing home residents have increased rapidly, rising by 20 percent between 1992 and 1994.

Table 1: Increasing Prescription Drug Payments for Texas Medicare and Medicaid Nursing home Residents			
YEAR	TOTAL PAYMENT	TOTAL BENEFICIARIES RECEIVING DRUGS	AVERAGE PAYMENT PER BENEFICIARY
1992	\$75,501,900	83,891*	\$900
1993	\$82,517,940	84,895	\$972
1994	\$91,584,609	85,111	\$1076
Percent Change	+21.3%	+1.45%	+19.6%

* 1992 figures projected using calculations based upon 1994 Medicare and Medicaid to total beneficiary ratio.

From 1992 to 1994 total drug payments have increased each year, rising much faster than the rate of increase in the number of beneficiaries receiving drugs (+1.5 percent) and at a substantially greater rate than the rate of inflation during this period.¹¹ As a result, there was a significant increase (20 percent) in the average payment per beneficiary during this period. The 1994 total represents just over 17 percent of the total Texas drug claims. A portion of this growth may be attributable to changes in treatment and practice patterns over this period. Recognition that older patients may benefit from a more aggressive diagnosis and treatment of depression, combined with higher costs of newer and potentially safer antidepressants, as well as increased use of more expensive cardiovascular and cardiac drugs, may have contributed to the increase.

In 1994, almost 20 percent, or more than 16,600, of Texas' Medicare and Medicaid beneficiaries received at least one of the twenty drugs experts consider potentially inappropriate for elderly use.

This is 19.6 percent of all beneficiaries in our dataset. Note, however, that although there is an overall increase in beneficiaries receiving all drugs in the five major cost categories (see Table 4), there is a downward trend in the percentage of beneficiary claims for *contraindicated* drugs (see Table 2). The rate of potentially inappropriate claims has declined from 21.2 percent in 1992 to 20.8 percent in 1993 to 19.6 percent in 1994. The trend appears to continue in 1995, as only 17 percent of Medicare and Medicaid beneficiaries receiving drugs had claims for one or more items on the list of contraindicated drugs. While this is encouraging, it is important to remember that the 1995 figures represent only claims from the first six months of the year, and it is likely that the final figure will be somewhat

higher for the full year. Regardless, the rate of resident use of contraindicated drugs remains high enough to be a continuing, serious concern.

YEAR	BENE WITH CONTRAINDICATED DRUG	BENE WITH ANY DRUG	% OF TOTAL
1992	15,623	73,814	21.2%
1993	17,617	84,584	20.8%
1994	16,670	85,111	19.6%
1995 (first 6 months)	12,460	73,328	17.0%

We searched our 1994 dataset for Medicaid payments for several specific drugs experts generally consider inappropriate for elderly use. The following discussion illustrates some of the concerns with these problematic drugs.

Examples of contraindicated drugs being used in Texas nursing facilities:

Dipyridamole

Just over ten percent of all the Medicare and Medicaid beneficiaries receiving any prescription drug in 1994 received dipyridamole. This drug falls into the cardiac category and is used to reduce blood clot formation. It is often prescribed in cases of cardiac valve replacement or to help prevent recurrence of myocardial infarction, or heart attack. Dipyridamole is also prescribed as treatment for transient ischemic attacks (TIAs) which can lead to blindness, paralysis, speech disturbance, or coma. Some experts express concern that the effectiveness of this drug at low doses is in doubt and that higher doses may lead to toxicity. They suggest that other, safer drugs are available.¹² Our data show Medicaid programs paid \$346,639 for this drug in Texas nursing facilities in 1994.

Psychotherapeutic Drugs

Of particular concern to medical experts and to Congress and the HCFA are drugs that fall into the psychotherapeutic class. Despite regulatory changes in the late 1980s mandating the reduction of the use of psychoactive drugs in nursing home patients, several recent studies indicate that about half of all residents were still being given one or more of these drugs as late as the mid 1990s.¹³ Consistent with this literature, in Texas nursing facilities 55.8 percent of Medicare and Medicaid residents received at least one of the drugs in 1994. During the first half of 1995 48.3 percent of beneficiaries received psychotherapeutics, indicating continued high usage of drugs in this category.

One of these psychotherapeutic drugs is diazepam, better known by its brand name, *Valium*. It is a long-acting benzodiazepine often used to treat dementia, anxiety disorders, and insomnia. A number of studies cite expert claims that there are other, shorter acting drugs in the same class that are more appropriate for use in the elderly¹⁴. One concern about the use of diazepam in this population is the tendency, because it remains in the system for quite a long time, for older folks to become oversedated and uncoordinated when given regular adult doses. Such effects are likely to result in injuries associated with falls. The HCFA guidelines, as well as the experts, recommend that physicians attempt to reduce the dosage of these drugs in elderly people until a minimal effective dose is reached. In 1994, Medicaid programs paid \$81,890 for Diazepam for a total of 2,911 Medicaid and Medicare Texas nursing home beneficiaries.

In the same year, Medicaid programs also paid \$159,630 for amitriptyline for 6,459 residents. Also within the psychotherapeutic classification, amitriptyline is used to treat depression. While there is some concern about the possible underuse of antidepressants in elderly individuals, experts worry about the number and severity of side effects associated with this particular drug. Moreover, some of these side effects can be misinterpreted as symptoms whose treatment might require additional psychoactive drugs. Finally, another long-acting benzodiazepine in the psychotherapeutic class, flurazepam, was the object of 953 claims for a total of \$19,317 in 1994.

Five drug categories account for an expanding majority of total payments for prescription drugs.

These drug categories consistently rank in the top five in terms of total payment for all of the years for which we have complete data. Also, their share of total payments has grown significantly from 1992 through the first half of 1995.

GENERAL CLASSIFICATION	1992	1993	1994	Percent Change
GASTROINTESTINAL PREPARATIONS	11.9%	15.3%	16.7%	+40.3%
CARDIAC DRUGS	10.4	11.5	12.1	+16.3
PSYCHOTHERAPEUTIC DRUGS	8.9	10.4	11.4	+28.1
CARDIOVASCULAR DRUGS	6.5	7.8	7.6	+16.9
ANTIINFECTIVES	4.6	5.7	5.5	+19.5
TOTAL	42.3	50.7	53.3	+26.0

Gastrointestinal preparations include drugs which are intended to treat ulcers, limit the secretion of certain gastrointestinal fluids, or to treat gastrointestinal reflux. Some of the most common brand names in this category include *Zantac* and *Pepcid*.

Cardiac drugs include recognizable brand names such as *Procardia*. This class of drugs is used in treatment of chronic angina pectoris and hypertension and in prevention of angina symptoms, such as chest pain and shortness of breath, as well as reduction of blood pressure.

Psychotherapeutic drugs, including *Prozac*, *Zoloft*, and *Paxil*, are used to treat a number of problems ranging from anxiety and depression to insomnia and agitation associated with dementia.

Cardiovascular drugs such as *Capoten* and *Vasotec* are used to treat blood pressure related ailments and congestive heart failure.

Finally, **antiinfective drugs** are used to treat a wide range of problems including urinary tract infections, bone and joint infections, pneumonia, infectious diarrhea, and skin and soft tissue infections, such as bed sores.

Additionally, more than 50 percent of all beneficiaries received drugs from at least three of the top five classifications in each year for which we have data.

From 1992 through 1994 over 50 percent of all Texas Medicare and Medicaid nursing home residents were reimbursed for at least one prescription from the cardiac, psychotherapeutic, and antiinfective drug categories.

Table 4: Percent of Total Beneficiaries Receiving Prescription Drugs			
GENERAL CLASSIFICATION	1992	1993	1994
ANTIINFECTIVES	58.8%	63.9%	63.5%
PSYCHOTHERAPEUTIC DRUGS	50.8	53.2	55.8
CARDIAC DRUGS	50.2	51.4	51.5
GASTROINTESTINAL PREPARATIONS	40.5	44.9	46.8
CARDIOVASCULAR DRUGS	27.7	28.2	28.9

Total payments for the top five categories of drugs increased very rapidly from 1992 through 1994. The proportion of total beneficiaries who receive them also grew.

From 1992 to the end of 1994 the proportion of total beneficiaries receiving gastrointestinal drugs rose more than 15 percent. With this increase in use came a major increase (94 percent) in the total payments for these drugs. Similarly, total payments for psychotherapeutic drugs rose nearly 92 percent, while the percent of total beneficiaries receiving these drugs increased by about 10 percent. Though not as high, the other three top categories also saw an increases of 60 percent or more in payments, coupled with moderate growth in the percent of total beneficiaries receiving them. To place this change in perspective, recall from Table 1 that total drug payments increased just over 21 percent from 1992 through 1994.

Table 5: Percent Change 1992-1994, Percent of Total Beneficiaries Receiving Prescription Drugs and Total Payment for Five Drug Classifications

GENERAL CLASSIFICATION	Percent Total Beneficiaries (% change)	Total Payment (% change)
GASTROINTESTINAL PREPARATIONS	+15.5%	+ 93.6%
PSYCHOTHERAPEUTIC DRUGS	+ 9.8	+ 91.8
CARDIOVASCULAR	+ 4.3	+ 60.2
ANTIINFECTIVES	+ 8.0	+ 63.8
CARDIAC DRUGS	+ 2.5	+ 59.6

Gastrointestinal preparations comprise an increasing proportion of the prescription drugs used in Texas nursing facilities. Closer scrutiny of the medical necessity of these very expensive drugs appears warranted.

Some experts in elderly health care are concerned about the increasing use of certain gastrointestinal drugs. Within this classification, Histamine-2 receptor antagonists have become a very popular treatment for many acid related gastrointestinal disorders including peptic ulcers and gastroesophageal reflux. Two of the most common of these drugs are cimetidine and ranitidine, better known as *Tagamet* and *Zantac*, respectively. A 1992 study conducted in a large long term care facility indicated that more than 40 percent of patients receiving these drugs were receiving them for reasons unsubstantiated by the medical literature.¹⁵

Because there are relatively few side effects associated with these drugs when prescribed in proper doses the concern about their use is not a major quality of care issue. However, it can become a significant cost issue. These particular drugs are very expensive. In fact, in 1994 Federal programs paid \$15,325,877 for gastrointestinal drugs. A total of 33,575 or almost 47 percent of all Texas nursing home beneficiaries received at least one gastrointestinal drug. *Zantac* accounted for \$5,921,810 of those payments while \$751,588 was for *Tagamet*. At more than \$380 per year per beneficiary, gastrointestinal drugs are also among the most expensive types of drugs covered by Federal programs. Thus, if 40 percent or more of these claims are not medically necessary, there should certainly be an economic benefit from reducing their inappropriate use.

Total prescription drug payments, average payments per day, and average payments per beneficiary vary quite widely by Texas nursing home. The reasons for, and appropriateness of, these variations are unclear.

Average 1994 prescription drug payments, when arrayed by nursing home, range from a high of more than \$8 per day per facility to as little as 17 cents per day. Payments per beneficiary in a particular facility begin at just over \$5 and increase to more than \$485. The

1994 data also reveal that the average total payment aggregated at the nursing home level is just over \$82,000. Total payments per facility range from under \$10 to more than \$335,000 for that year. Almost 10 percent of facilities had total resident reimbursements under \$10,000, while 30 percent of facilities had total reimbursements of more than \$100,000. Table 6 illustrates the variation in prescription drug payments when considered at the facility level.

Table 6: 1994 Average Prescription Drug Payments; Totals, Per Beneficiary, and Per Day (by Nursing Home)			
	MINIMUM	MAXIMUM	MEAN
TOTAL PAYMENT (per facility)	9.89	336,539	82,939
AVERAGE PAYMENT PER BENEFICIARY (per facility)	5.26	487.23	158.95
AVERAGE PAYMENT PER DAY (per facility)	0.17	8.82	0.73

*For this analysis, facilities with fewer than 5 beneficiaries were excluded. Also, one extreme case, whose average payment per day value is 60 percent higher than the next lowest value, was omitted.

While some of these differences are certainly attributable to the number of beneficiaries residing in a particular facility, it is likely that other factors also contribute to the variation. However, our existing data does not reveal a relationship that explains these differences. When claims data for a particular class of drugs are arrayed by nursing home, no characteristics consistently differentiate those with high costs per beneficiary or per day from those with lower costs. Following the compilation of additional data, we plan further analysis to determine what other variables, such as facility type, severity of resident illness, and types and numbers of other services, contribute to these wide differences in payments at the nursing home level.

RECOMMENDATIONS

Based on the concerns raised in this report, more work is necessary to understand reasons for the rapid escalation in costs and claims for certain types of drugs used in nursing homes. Specific recommendations for HCFA to consider in this endeavor are provided in our third report of this inspection, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06-96-00082).

COMMENTS ABOUT DRAFT REPORTS

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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 the third and final report of this inspection, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06-96-00082).

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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 the third and final report of this inspection, "A Pharmaceutical Review and Inspection Recommendations" (OEI-06-96-00082).

ENDNOTES

1. Once we identified the dually-eligible population, we extracted Medicaid payments for drugs provided during a nursing home stay from data currently maintained by HCFA or the OIG. Only the first six months of claims data were available for 1995. These figures are included in our analysis where appropriate. Due to the difficulty in estimating the nursing facility population for the full year, no attempt was made to project these figures beyond June 30, 1995.
2. Health Care Financing Administration, BDMS Division of Medicaid Statistics, 1996.
3. HCFA, BDMS, OSM, Division of Program Systems, 12/19/1996.
4. Keitz, Todd. "10 Things You Should Know About the Long Term Care Market." *Medical Marketing and Media*. 30(5):42-46. May 1995.
5. 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.
6. 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.
7. Spore DL, Mor V, Larrat P, Hawes C, Hiris J, "Inappropriate Drug Prescriptions for Elderly Residents of Board and Care Facilities." *American Journal of Public Health*, Vol.87, No. 3 (March 1997), pp. 404-409.
8. 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.
9. 42 CFR Sec 483.60.
10. Ukens, Carol. "Warning Sign." *Drug Topics*. 139 (13); 56 July 10, 1995.
11. The inflation rate based on the Consumer Price Index was just over 6 percent for this period and 6.7 percent based upon the CPI: Medical Index for Prescription Drugs. Thus, the adjusted growth rate for average payments per beneficiary remains approximately 13 percent based upon either index.
Source: Bureau of Labor Statistics, U.S. Department of Labor
12. Beers, et al. 1991; Avorn and Gurwitz, 1995.
13. Avorn and Gurwitz, 1995., Beers, Ouslander, et al.,1992.

14. GAO, July 24, 1995; Beers, et al, 1991; Avorn, Jerry and Jerry H. Gurwitz. "Drug Use in the Nursing Home." *Annals of Internal Medicine*, Vol 123 (August, 1995), pp. 195-204.
15. Gurwitz, JH, JP Noonan, and SB Soumerai. "Reducing the Use of H2-Receptor Antagonists in the Long-Term-Care Setting," *Journal of the American Geriatric Society* 1992; Vol 40 pp.359-64.

APPENDIX A

20 Drugs Generally Considered 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, 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.

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

General Classification of Prescription Drugs

Analgesics

- Analgesics, narcotic
- Analgesics, non-narcotic general
- Antidotes

Anesthetics

- Anesthetic local/topical

Antiarthritics

Antiasthmatics

- Bronchial dilators
- Xanthine derivatives

Antihistamines

- Antihistamines
- Antipruritics

Antiinfectives

- Tetracyclines
- Penicillins
- Streptomycins
- Sulfonamides
- Erythromycins
- Cephalosporins
- Antibacterials, urinary
- Chloramphenicol
- TB preparations

Antiinfectives, miscellaneous

- Antimalarials
- Trimethoprim
- Vaginal cleaners

Antineoplastics (anti-tumor)

Antiparkinson drugs

Autonomic drugs

- Cardiovascular preparations, other
- Parasympathetic agents

Blood

- Anticoagulants
- Hemostatics

Cardiac drugs

Vasodilators, coronary
Digitalis preparations

Cardiovascular

Aldosterone antagonists
Lipotropics
Cholesterol reducers
Rauwolfias
Hypotensives, other
Vasodilators, peripheral

CNS drugs (central nervous system)

Anticonvulsants

Contraceptives

Cough and cold preparations

Antitussives-expectorants
Cough and cold preparations
Adrenergics

Diuretics

Electrolyte, caloric and fluid replacement

Iodine therapy
Protein lysates
Electrolytes & miscellaneous nutrients
Hematinics

EENT preparations (eye, ear, nose, and throat)

Nasal and otic preparations, topical
Ophthalmic preparations

Gastrointestinal preparations

Anti-ulcer/other gastrointestinal preps
Antidiarrheals
Antispasmodic-anticholinergics
Bile therapy
Laxatives
Antinauseants
Digestants
Hemorrhoidal preparations

Hormones

Corticotropins
Mineralocorticoids
Anabolics
Androgens
Estrogens
Progesterone
Other hormones
Oxytocics

Hypoglycemics

Misc. Med. Supplies, devices & other non drug

Medical supplies, devices and other non-drug products

Muscle relaxants

Psychotherapeutic drugs

Ataractics-tranquilizers

CNS (central nervous system) stimulants

Psychostimulants-antidepressants

Sedative and hypnotics

Sedative, barbiturate

Sedative, non-barbiturate

Skin preparations

Antibiotics, other

Antiparasitics

Antivirals

Antibacterials and antiseptics, general

Glucocorticoids

Enzymes

Emollients, protectives

Fungicides

Dermatologicals, all other

Thyroid preps

Thyroid preparations

Antithyroid preparations

Biologicals

Pre-natal vitamins

Multivitamins

Vitamins, all others

Vitamins, fat soluble

Folic acid preparations

B complex with vitamin c preparations

Vitamin k preparations

Unclassified drug products