

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PRESCRIPTION DRUG USE
IN NURSING HOMES**

Report 2

An Inside View by Consultant Pharmacists



**JUNE GIBBS BROWN
Inspector General**

**NOVEMBER 1997
OEI-06-96-00081**

EXECUTIVE SUMMARY

PURPOSE

To describe consultant pharmacists' concerns about drug usage in nursing homes and their perceptions of their responsibilities for medication reviews for nursing home residents.

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. As such, these pharmacists are a valuable source of information. To take advantage of their experience, we surveyed a statistically valid sample of pharmacists drawn from a stratified random sample of the 17,000 nursing facilities.

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 second. This report presents the results of an in-depth, structured mail survey of these consultant pharmacists.

The first report, "An Introduction Based on Texas" (OEI-06-96-00080), describes prescription drug use in nursing homes based on Texas data. 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

Quality of Care Issues

Overall, pharmacists tell us they and the nursing homes are complying with the law and regulations related to medication reviews of nursing home residents. However, problems and concerns raised by the consultant pharmacists indicate that legislative and regulatory intentions to assure high quality pharmaceutical care for nursing home residents are not yet fully realized. 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.

According to pharmacists, patients are experiencing numerous adverse reactions as a result of potentially inappropriate prescribing and inadequate administration or monitoring of the usage of medications.

Adverse reactions reported by consultant pharmacists as occurring sometimes or often include constipation (reported by 81 percent); falls (66 percent); delirium (41 percent); depression (39 percent); and urinary incontinence (26 percent).

Pharmacists have serious concerns about prescribing practices for antipsychotics, anxiolytics, sedatives/hypnotics, antidepressants, and other drugs.

Because legislation prescribes certain limitations on antipsychotics, anxiolytics, and sedatives/hypnotics, there is concern that from 21 to 44 percent of pharmacists report some patients are receiving medically inappropriate prescriptions of these drugs. Other drugs, not necessarily legislated for scrutiny, which also seriously concern consultant pharmacists include H2 antagonists (reported by 65 percent); non-steroidal anti-inflammatory drugs (47 percent); narcotics (46 percent); digoxin (40 percent); antibiotics and anti-infectives (39 percent); and gastrointestinals (36 percent). Moreover, according to 15 percent of the consultant pharmacists, some physicians are prescribing medically inappropriate antidepressants. One-third say antidepressants are sometimes prescribed without an appropriate diagnosis and that few or no physicians ensure their maintenance at appropriate levels.

A number of medication administration problems which may put patients at risk also concern pharmacists.

These include absence of specific usage directions; incomplete orders; failure to update medication administration records with dosage or schedule changes; physicians signing orders that are not current or correct; failure to include orders on the medication administration record; misplaced medications; and continuation of a medication in disregard of stop orders. Further, medications are sometimes administered by nursing staff at the wrong time, in non-optimal dosages, for inappropriate durations, or the medication may be inappropriately altered (crushing, dilution, etc.).

Shortcomings of Medication Reviews

While all consultant pharmacists report they conduct monthly drug regimen reviews, their responses indicate some serious shortcomings in the quality and thoroughness of reviews.

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

More than half of the reviews do not consider the resident's assessment (65 percent) or plan of care (56 percent). Other records not consulted by pharmacists include facility incident and accident reports (20 percent) and specialists' notes and nutritional plans (13 percent). Fully one-third say they have difficulty obtaining a patient's diagnosis and necessary lab reports.

The results of drug regimen reviews often are not documented in records readily available to nursing home staff.

While one-third of pharmacists say they document medication reviews and related contacts in the patients' medical records or medication charts, many do not document their efforts in records most accessible to nursing home staff.

There is an apparent need to strengthen pharmacists' relationships with patients and direct care staff and also their performance of educational and counseling activities.

Many pharmacists have no contact with patients or their families or with nurse aides in their conduct of drug regimen reviews. Also, over two-thirds report not providing education or training for either patients or their families or guardians; nearly half do not provide drug education for nurse aides or medication aides; and, despite the potentially critical interaction between diet and medications, most pharmacists have no contact with the facility dietician.

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 improve the effectiveness of medication reviews for patients in nursing homes. Recommendations to accomplish this are provided in the third and final report of this inspection, "A Pharmaceutical Review and Inspection Reports" (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.

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).

TABLE OF CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION 1

Regulation and control of prescription drugs in nursing homes 2

Role of consultant pharmacists 3

Physicians determine what is appropriate for patients 4

Challenge of prescribing for the elderly 5

SCOPE AND METHODOLOGY 6

FINDINGS 9

Quality of Care Issues 9

Shortcomings of Medication Reviews 14

RECOMMENDATIONS 21

COMMENTS ABOUT DRAFT REPORTS 22

ENDNOTES 24

APPENDICES

Inappropriate Medications for Elderly Persons A-1

Consultant Pharmacists' Assessment of Medication Problems (Weighted Data) B-1

Additional Pharmacist Survey Weighted Data Tables C-1

INTRODUCTION

PURPOSE

To describe consultant pharmacists' concerns about drug usage in nursing homes and their perceptions of their responsibilities for medication reviews for nursing home residents.

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). Equally effective drugs which present fewer risks may be available.⁹

Regulation and Control of Prescription Drug Use in Nursing Homes

Omnibus Budget Reconciliation Act of 1987

As part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), Congress requires the regulation 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 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 these reviews, HCFA developed "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" and "Surveyor Methodology for Detecting Medication Errors." They also released revised interpretive guidelines relating to medication use 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. Further, in July 1995,

HCFA implemented the final step in the implementation of OBRA 1987, 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.

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. Each pharmacist's relationship with nursing home patients requires their refocusing from a product orientation (distribution of medications) to that of a clinical practitioner responsible for reducing potential medication problems. Both our literature review and the consultant pharmacists themselves confirmed that moving to a patient-focused

orientation has required breaking with traditional dispensing roles and utilizing those clinical skills for which many pharmacists are now routinely being trained. This changing orientation within the industry helped strengthen the argument for using pharmacists in nursing homes to more effectively assist in medication changes which could positively impact a patient's quality of care.

To ensure compliance with the OBRA regulations, nursing facilities are expected to employ consultant pharmacists. These consultant pharmacists 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 benefits potentially realized as a result 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 medication being prescribed, and fewer costly adverse reactions being experienced.

In addition to detecting quality of care concerns associated with inappropriate medication usage, consultant pharmacists may detect potential waste and abuse which can increase costs to the programs. Duplicate prescriptions and the early renewal of maintenance prescriptions increase program costs in the form of additional dispensing fees and could be signs of possible diversion or resale of prescription drugs. The required destruction of numerous drugs upon the death, discharge, or change in treatment plan of a nursing home patient may also result in greater expenses than necessary.

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.¹³ 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 Elderly¹⁴

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, overdosage, 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.

SCOPE AND METHODOLOGY

Focus of Report

In 1996, the OIG 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 a sample of residents to determine the appropriateness of prescription drugs utilized and to examine the extent of selected drug use problems.

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. This report, focusing on the second component of the project, identifies problems and concerns raised by consultant pharmacists. 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.

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.

Survey of Consultant Pharmacists

Because consultant pharmacists are responsible for a monthly medication review of nursing home patients, they serve as a valuable source of information. To take advantage of their experience, we surveyed a statistically valid sample of pharmacists drawn from a stratified random sample of the 17,000 nursing facilities.

In order to be able to discuss issues related to the Presidential initiative, Operation Restore Trust (ORT), stratification was based on whether the nursing home is in an ORT State. This resulted in six strata - one for each of the five ORT States (California, Florida, Illinois, New York, Texas) and one for non-ORT States. We randomly selected 150 nursing homes for each of the six strata resulting in a sample of 900 facilities. Each of the 900 nursing facilities sampled was contacted directly to obtain the name of its current consulting pharmacist providing drug regimen reviews for the nursing home's patients.

A structured, in-depth mail survey asked pharmacists to provide sufficient information to determine 1) whether and to what extent drug regimen reviews are being conducted, 2) other services which pharmacists may be providing, 3) constraints of the review process, and 4) their views about medication use problems in nursing facilities.

Their responses were solicited with certain parameters:

- 1) Pharmacists were asked to randomly select a single home for which they would provide information (this home was not necessarily the sample home from which we identified the pharmacists);
- 2) We asked that they answer all questions throughout the survey with that one home in mind;
- 3) Pharmacists were to have at least six month's personal and continuous experience providing consultant pharmacy services to the nursing home about which they were responding;

- 4) The nursing home should include predominantly Medicare and Medicaid residents (some private pay as well); and
- 5) The responses were to be reflective of their activities for the six month period prior to their receipt of the survey.

Our original response rate for returned surveys mailed was 76 percent (682 of 900). However, in our decision to take a conservative approach, we dropped 221 returned surveys because some nursing facilities were determined to be duplicates as a result of name changes, misspellings, etc.; pharmacists being identified as servicing more than one sample facility; and some facilities closing subsequent to the review period. The remaining 461 surveys (75 percent ORT and 25 percent non-ORT) represent 51 percent of the original 900 and provide the basis for the findings of this report.

Confidence levels were computed for selected variables using SUDAAN. At the 95 percent level, confidence intervals were no greater than ± 8 percent for most survey responses. The data reported in our findings have been weighted to reflect responses received from pharmacists representing each ORT State or the other, non-ORT States. Assuming that the pharmacists did in fact randomly select the facility for which they provided information (including those pharmacists who were identified for more than one facility), we can generalize our findings to encompass all consultant pharmacists who have responsibilities for nursing home patients.

This evaluation was conducted as part of ORT, 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.

Our 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, pharmacists tell us that they and the nursing homes are complying with the law and regulations related to medication reviews of nursing home residents. However, the problems and concerns raised by the consultant pharmacists indicate that legislative and regulatory intentions to assure high quality pharmaceutical care for nursing home residents are not yet fully realized.

Pharmacists believe that nursing home patients are experiencing numerous adverse medication reactions as a result of inadequate monitoring of medications and inappropriate prescribing practices.

Consultant pharmacists, who advocated for and received increasingly responsible roles under OBRA 1987 and OBRA 1990, believed they could play a vital role in assuring quality care for nursing home patients. Arguably, pharmacists' professional education gives them valuable expertise and clinical knowledge concerning pharmacotherapy. Critical to this expertise and extremely important for the nursing 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. Many pharmacists report eight problems regarding monitoring of patients' medications which sometimes occur:

- 1) no lab testing to ensure continued need for the medication (61 percent);¹⁵
- 2) failure to chart drug usage (59 percent);
- 3) medication to medication interactions not detected (57 percent);
- 4) no lab testing to monitor potentially toxic drugs (51 percent);
- 5) failure to adjust dosages for renal/hepatic function (50 percent);
- 6) no monitoring for efficacy or side effects (50 percent);
- 7) no physical functioning assessment of patient to check either for correct dosage or continued need for the medication (47 percent); and
- 8) no physical assessments for routine monitoring of certain drugs (43 percent).

Additionally, a large number of consultant pharmacists are concerned that medications being prescribed to patients contribute to patients' constipation (reported by 81 percent of pharmacists); falls (66 percent); delirium (41 percent); depression (39 percent); and urinary incontinence (26 percent).¹⁶

Many drugs other than psychotropics are also psychoactive, in the sense that they may affect a patient's cognition, balance, and motor coordination, as well as pulse and blood pressure. Unfortunately, elderly patients have an increased risk of falls if they experience a combination of several certain ailments or medications.¹⁷ One key to monitoring for these and other potential effects is the extent to which physicians have communicated their

expectations to conduct such monitoring, i.e., in their orders prescribing care for the patient or in progress notes, and the extent to which the nursing staff is able to accurately report the results of any such monitoring.

Another factor directly linked to the effectiveness of such monitoring is the cooperation, coordination, and communication between all the key persons involved in the care of the patient. Cooperative healthcare team work requires routine interaction between the involved team members. In the case of the nursing home, it will at least require communication between medical, nursing, and pharmaceutical personnel and include the patient as well as other nursing home staff. However, it can be extremely difficult to get all the team members together routinely. This is complicated by the fact that such meetings are not required. Thus, the means and opportunity for communication (written or verbal) between the involved personnel becomes more critical. Written communication becomes even more necessary when at least two of the critical players (physician and consultant pharmacist) do not frequent the home regularly and rarely interact directly with each other. It becomes difficult to ensure that the necessary engagement between players occurs, and without clear communication, cooperation will be extremely hard to develop between these critical players.

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.

Twenty-eight percent of the pharmacists report residents' physicians only sometimes give serious consideration to their concerns. Similarly, 35 percent of consultant pharmacists say doctors only rarely or sometimes take prompt action on their recommendations about a *specific resident's prescriptions or medication regimen*, although 65 percent say that those physicians who do take action do so promptly. Further, while 43 percent of consultant pharmacists say physicians act promptly on their recommendations about *patterns in the physician's prescribing practice*, many consultant pharmacists say they only do so sometimes (45 percent) or rarely (11 percent). By contrast, 99 percent of the consultant pharmacists say nurses seriously consider their concerns most to all the time. Further, over 90 percent of the pharmacists agree that both personal physicians and nursing staff *should* routinely solicit their help regarding appropriate medications and dosages.

A majority of pharmacists say personal physicians rarely or never seek their help regarding either the appropriate medications (reported by 68 percent) or proper dosages for medications (59 percent). In contrast, consultant pharmacists say nurses sometimes to often seek their help with medications (reported by 75 percent) or dosages (89 percent). For the most part, pharmacists report receiving very good to good cooperation from the nursing directors (95 percent), nursing staff (94 percent), and nursing home administrators (83 percent). However, they rate the cooperation of patients' personal physicians and the facility medical directors somewhat lower, with only 57 percent and 72 percent, respectively, rated as good to very good.

According to many of the surveyed consultant pharmacists (55 percent), their medication reviews are more complicated because 50 percent or more of their patients are frail elderly (85 years or older). While 56 percent of the pharmacists say that physicians are adequately aware that certain medications are considered inappropriate for use by this age group, 29 percent state that physicians are not adequately aware of the special medication needs of these patients; another 15 percent did not know. As a result, pharmacists fault some physicians' lack of awareness concerning the medication needs of elderly nursing home patients and the resulting consequences of prescribing without such awareness.

Pharmacists have serious concerns about specific prescribing practices related to antipsychotics, anxiolytics, sedatives/hypnotics, antidepressants, as well as other prescription drugs.¹⁸

The law specifies that patients have the right to be free from any medication imposed for the purposes of discipline or convenience, and not specifically required to treat medical symptoms. It also requires that any use of antipsychotic medications be based on a comprehensive assessment of the patient. In fact, some experts recommend that any patient using such drugs receive gradual dose reductions, have drug holidays (for which there are no Federal guidelines as to which drugs or for what dosages or durations), or receive behavioral programming in an effort to discontinue or reduce the dosage of these medications. Because legislation prescribes these and other limitations on antipsychotics, antianxiety medications, and sedatives/hypnotics, there is concern that from 21 to 44 percent of pharmacists report some patients are receiving medically inappropriate prescriptions of these drugs.

Further, consultant pharmacists report that of those physicians prescribing antidepressants, sedative/hypnotics, antianxiety agents, and antipsychotics, many are not attempting to achieve the lowest effective doses. Specifically, few physicians are attempting to achieve the lowest effective doses for antidepressants (reported by 42 percent of pharmacists); sedative/hypnotics (21 percent); anxiolytics (14 percent); and antipsychotics (10 percent). Important among the reasons pharmacists believe physicians are not limiting their prescribing of inappropriate medications, is the pressure to continue the medications from the patient's family or guardian (28 percent), the patient (24 percent), and the facility staff (14 percent). Lack of physician knowledge (21 percent) or training (15 percent) are also noted by consultant pharmacists, along with perceived indifference by the physician responsible for ensuring the patient's care (21 percent).

	Antipsychotics	Anxiolytics	Sedatives/ Hypnotics	Antidepressants
Patients Inappropriately Receiving				
% Consultant Pharmacists Reporting Yes	33	35	44	21
% Consultant Pharmacists Reporting No	67	65	56	79

We are aware that HCFA has committed to goals of decreasing patient usage of antipsychotics and antianxiety medications while increasing the use of antidepressants when appropriately necessary. Recent studies indicate that the OBRA's 1987 and 1990 regulations may have helped to achieve such a reduction for antipsychotic drug use in this population. Preliminary data collected by HCFA on nursing homes in three test States indicate a shift in usage from antipsychotics to antidepressant medications. Specifically, the data illustrates an average decrease of 17 percent in the use of antipsychotics and an increase in antidepressant (77 percent) and hypnotic/sedative (27 percent) drug use.¹⁹

We should note that a considerable number of consultant pharmacists indicate appropriate prescribing practices for antipsychotics (46 percent); anxiolytics (44 percent); sedatives/hypnotics (38 percent); and antidepressants (57 percent). Yet, it is significant to note that from 1-6 percent of the consultant pharmacists say these four drug categories are inappropriately prescribed by most or all physicians; an additional 9-17 percent say some physicians are inappropriately prescribing these medications to nursing home patients. Table 2 reflects how many physicians consultant pharmacists believe are inappropriately prescribing these categories of medications.

Medication Type	% None	% Few	% Some	% Most	% All
Antipsychotics	46	42	10	2	1
Anxiolytics	44	38	16	3	0
Antidepressants	58	29	9	4	2
Sedatives/Hypnotics	38	42	17	3	1

In addition to the four drug categories discussed, consultant pharmacists also have serious concerns about patient usage of other medications including the following:

<u>Medication Type</u>	<u>% Consultant Pharmacists Sometimes or Often Concerned</u>
1) H2 Antagonists	65
2) Non-steroidal Anti-inflammatory drugs	47
3) Narcotics	46
4) Digoxin	40
5) Antibiotics and Anti-infectives	39
6) Gastrointestinals	36

According to 15 percent of the consultant pharmacists, some physicians are prescribing medically inappropriate antidepressants, and 33 percent indicate concern that antidepressants are prescribed without an appropriate diagnosis.

Again, it is important to understand that “inappropriate” may also mean *insufficient* amounts rather than too much or a wrong type of medication. While 42 percent of consultant pharmacists report most or all physicians attempting to limit or reduce the dosage of these drugs, literature and research indicate that many physicians may be limiting antidepressants too much when a higher dosage would actually be more effective for depression. This was confirmed by consultant pharmacists reporting that when a diagnosis of “depression” is available, some (25 percent of pharmacists report) or most (6 percent) physicians may be prescribing sedatives or hypnotics when antidepressants should be used in the treatment of depression.²⁰

Thirty-four percent of the consultant pharmacists express concern that physicians do not ensure the continued maintenance of appropriate levels of antidepressants.

Treatment of depression must begin with a comprehensive evaluation of the older person. This assessment will rule out any associated medical or physical conditions which may present symptoms of depression or which may complicate the treatment of depression. This includes reviewing laboratory studies, including a complete blood cell count; liver function tests; serum albumin levels, thyroid function tests. Also, all current medications should be reviewed in light of any lab tests and symptoms being exhibited by the patient.

Consultant pharmacists also expressed concerns about other potentially inappropriate medication usage by nursing home patients:

<u>Medication Issue</u>	<u>% Consultant Pharmacists Sometimes or Often Concerned</u>
1) Prolonged use of sleeping medicines	76
2) Overutilization of drugs	62
3) Use of “as needed” drugs for too long	61
4) Use of antipsychotics without a diagnosis	45
5) Use of contraindicated drug for patient’s existing diagnosis or disease	26

A number of medication administration issues are also problems according to consultant pharmacists.

These include absence of specific usage directions (reported by 60 percent of pharmacists); incomplete orders (52 percent); failure to update the medication administration record with dosage or schedule changes (29 percent); physicians signing orders that are not current or correct (27 percent); and failure to include orders on the medication administration record (18 percent). These concerns may actually result in medications or treatment either occurring when unnecessary or being needed and not occurring at all (each of which may be grounds for citing immediate jeopardy for the patient not receiving the necessary care). Also, misplaced medications (22 percent) and continuation of a medication in disregard of stop orders (17 percent) also sometime concern consultant pharmacists.

Approximately half of the surveyed consultant pharmacists state that medications are sometimes administered by nursing staff at the wrong time (reported by 59 percent), in non-optimal dosages (53 percent), for unsuitable durations (47 percent), or the medication may be improperly altered (crushing, dilution, etc.) (40 percent). Much less frequent administration concerns include administering the wrong medication (11 percent) or giving a medication to the wrong resident (4 percent). Any of these concerns can have potentially serious implications, both for the efficacy of the drug and a patient's well-being. Yet, about 59 percent of pharmacists express concerns for their lack of authority to modify a resident's drug regimen, order lab tests to assure an appropriate medication regimen (66 percent), or to ensure doctors are prescribing appropriately (62 percent). Consultant pharmacists are also concerned that doctors are not required to respond to their concerns (reported by 54 percent pharmacists) or may reject their recommendations (47 percent), even though the consultant pharmacist is required to notify the physician and director of nursing of any problems.

SHORTCOMINGS OF MEDICATION REVIEWS

While all consultant pharmacists report they routinely conduct medication reviews, their responses indicate some serious shortcomings in the quality and thoroughness of reviews.

Some consultant pharmacists say they do not routinely participate in comprehensive patient assessments or in reviews of each patient's plan of care when opportunity allows.

Section 483.20 of CFR 42 requires that nursing facilities conduct a comprehensive patient assessment at admission and promptly after a significant change in the patient's condition. This assessment includes diagnosis(es), special treatment needs, recommended medication and nutritional therapy, cognitive, physical, behavioral, and psychosocial patterns, and other related health conditions. The assessment should occur at least once every 12 months, and nursing facilities must perform a *review* of the assessment at least every 3 months, and as appropriate, revise the patient's assessment. This, in turn, could affect each patient's plan of care. Also, OBRA 1987 Section 483.460(j)(5) states that "as

appropriate" the pharmacist must participate in the development, implementation, and review of each patient's plan (either in writing or in person).

More than half the consultant pharmacists state they do not routinely review a patient's medication regimen against either the Resident Assessment (65 percent) or the Plan of Care (56 percent), although both are available.

As discussed above, the patient's assessment identifies critical information for the medical, nursing, and pharmaceutical healthcare team. The plan of care is prepared by an interdisciplinary team, which should include the attending physician, a registered nurse with responsibility for the patient, and "other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative."

Further complicating the possible outcomes of the medication reviews, even though pharmacists indicate that most records necessary for conducting a medication review are readily available, some very important records are sometimes not available. Additionally, other important, available medical records may not be used by the consultant pharmacist. Most consultant pharmacists indicate no difficulty obtaining physician orders (reported by 94 percent of pharmacists), medication administration records (89 percent), or physician progress notes (87 percent).

	% Yes	% No
Against plan of care	44	56
Against resident assessment	35	65
Upon readmission from hospital	81	19
Upon changes to doctor's orders or resident's plan of care	75	25

Plans of care and patient assessments provide much of the necessary information for a pharmacist to identify any factors which may be negatively affecting a patient's medication regimen. Yet 48 percent of the consultant pharmacists report they have (at times) been prevented from performing a complete medication review because of lost or misplaced records. However, only 21 percent of the consultant pharmacists say that lack of complete, accurate medication records is a barrier to their ability to ensure an appropriate medication regimen for each patient.

While 80 percent of consultant pharmacists have no difficulty in obtaining a facility's incident or accident reports related to patients, 20 percent indicate they do not use them as part of the drug regimen review process. Such reports may be indicative of negative medication symptoms occurring and resulting in, for example, falls. Further, an analysis or summary monthly report by the facility might prove useful for identifying patterns of concern (e.g., patients on psychotropic drugs being the most prone to falls; falls occurring

more often during a late night shift; etc.). Further, approximately 13 percent of the consultant pharmacists indicate they do not use either specialists' notes or nutritional plans to assist them in determining whether there may be a related contraindication or impact on the patient's medication usage.

More than one-third of consultant pharmacists indicate they have difficulty in obtaining the patient's diagnosis. Additionally, 33 percent indicate difficulty obtaining any related laboratory reports, and some have problems getting hospital reports (30 percent) and patient discharge summaries (25 percent).

It should be understood that pharmacists and nursing staff should have available at least one of the following three documents from which to obtain a patient's diagnosis - the Minimum Data Set which identifies a patient's chronic diagnostic conditions; the patient's personal assessment; or the patient's plan of care addressing any chronic or acute diagnoses. Without at least one of these records being available, complete, and accurate, consultant pharmacists will not have the necessary information for confirming existing conditions for each diagnosis, identifying subsequent medication regimen actions for treating a patient's disease, or for continuing assessment of the patient's health. Without this information, pharmacists can meet only a portion of their professional responsibility to the patients.

With an incorrect diagnosis, or no available diagnosis, pharmacists are working in a void, one in which a wrong therapy may be initiated. For example, an older female patient may be exhibiting signs and symptoms of depression that may be caused by hypothyroidism. In this case, it would be improper to treat the symptoms with an antidepressant. Yet, without the required lab work, one may not realize the need for thyroid medication. Thus, in treating the symptom (depression) with an antidepressant instead of the cause (hypothyroidism) for the symptom, an incorrect or unnecessary therapy could be initiated, one which perpetuates the problem and may also cause additional perceived signs of senility (confusion, lapses in memory, difficulty communicating, etc.)

While one-third of pharmacists say they document medication reviews and related contacts in the patients' medical records or medication charts, many do not document their efforts in records most accessible to nursing home staff.

Pharmacists have long understood and accepted the need to document any form of dialogue noting, at a minimum, the fact that the dialogue occurred, with whom, the date, and the issue discussed. Nursing facilities maintain many types of files related to patient care and related activities. As indicated below, many of the consultant pharmacists do not *routinely* document their contacts or meetings related to patients' medication regimens in these records.

Type Records Used for Consultant Pharmacist Documentation	% Yes	% No
Daily Nursing Notes	5	95
Medical Records	31	69
Records of Dispensing Pharmacy	32	68
Patient's Plan of Care	4	96
Patient's Assessment	4	96
Consultant Pharmacist (Own) Records	97	3
Medication Chart	34	66

During a related review, we asked nursing facilities to provide certain necessary records for performing a desk review of a sample of patients' medication regimens. Many of the facilities had difficulty providing the records of the pharmacy consultants because they were maintained by the pharmacists in another location. Regardless of the potential lack of documentation, explicitly required of facilities by HCFA, fully 98 percent of the consultant pharmacists having recommendations from their most recent reviews say they voiced those recommendations to the nursing staff or physicians.

A complicating factor in conducting medication reviews is that pharmacists report most patients take six prescription medications on average.

This supports what the literature stated, that nursing home patients receive more medication than non-institutionalized older persons.²¹ Also, the number of prescriptions can range to as many as twelve or more, resulting in extremely complex reviews. In addition to the prescribed medications, pharmacists report patients may also be scheduled or routinely taking an average of three PRN ("as needed") medications. These PRN medications exceed 15 for some individuals. Thus, the average number of medications can range from 9 to beyond 20. This is important because the elderly use more prescription drugs than any other age group and are more likely to be taking multiple drugs, some of which may be inappropriate and result in particularly acute problems. This polypharmacy increases the probability of adverse drug reactions, creating a complicated regimen for pharmacists to review and understand, let alone communicate recommendations concerning such regimens.

Yet, the American Society of Consultant Pharmacists, in which many of the nursing home consultant pharmacists have membership, indicates each consultant pharmacist completes from four to six patient reviews per hour. This time incorporates all other activities for which the consultant pharmacist is responsible in the nursing home, (e.g., meetings, training, etc.). Average review time may be somewhat longer for patients requiring skilled or hospice care or having a large number of medications.²² Similarly, the consultant pharmacists in our survey indicated averaging four patient reviews per hour for monthly visits (this time is based on a 32 hour week, a 4.33 week month, and reported median numbers of patient reviews monthly).

It is also possible that not all medications a patient may be taking are included in the pharmacists' medication reviews.

The consultant pharmacists identified many barriers to their including non-prescribed medications in their medication reviews for each patient. Despite their importance as part of a patient's overall health and drug regimen, consultant pharmacists say their review of such medications is limited by such factors as their nursing home contract not specifying these drugs as part of the review and non-prescribed medications not being included in either the assessment, plan of care, or the permanent medical record for each patient. Further, many consultant pharmacists say records on non-prescribed over-the-counter medications are usually insufficient or not available and that collecting data on their use from patients or guardians is too labor intensive (see Appendix B, table 10).

A majority of the consultant pharmacists say they routinely maintain medication control, destruction, and quality records.

Virtually all consultant pharmacists (96 percent) monitor for expired medications, proper storage, and integrity of packaging of medications received in the nursing home; 84 percent maintain a system of records for medications received, administered, and destroyed. Fifty-four percent of the pharmacists also report they *personally* maintain or review a log of destroyed medications for each facility they serve. The primary reasons listed by consultant pharmacists for medications being returned for destruction include the patient's death (83 percent); discontinuing therapy (40 percent); discharging the patient (24 percent); and changing the medication (20 percent). Eight percent listed the expiration date of the medication; only 1 percent indicated the transfer of the patient as the primary reason for destroying medications. Additionally, nearly 12 percent of the consultant pharmacists say they sometimes encounter overcharging for medications dispensed.

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.

Many consultant pharmacists (89 percent) do not participate in patient care planning committees.

A majority of consultant pharmacists are participants of facility committees to ensure quality care (87 percent), pharmacy and therapeutics (74 percent), and infection control (67 percent). However, fully 89 percent do not participate in the facility's patient care planning committee. Further, while most consultant pharmacists have routine contact with the medical professionals involved in patient care (facility nursing director, nursing staff, and patient's personal physician), few routinely meet with the patient (18 percent), the primary individual for whom they are conducting the review. Only 12 percent contact a

patient when a problem with his/her medication regimen is encountered. Even fewer (five percent) report having routine contact with the patient's family or guardian when a problem is encountered with a patient's medication regimen. Also, despite the impact of diet on medications, less than half of the pharmacists routinely contact the facility dietician (43 percent) and few consultant pharmacists have routine contact with either the nurse aides (18 percent) or other therapists (25 percent) regarding patients under review. Thus, there appears to be a need to strengthen pharmacists' relationships with patients and direct care staff and also their performance of educational and counseling activities.

Approximately 93 percent of the consultant pharmacists routinely participate in drug education and training of nursing staff, but many do not provide such training to patients, their families, or the nursing home's aides.

OBRA 1987 requires training of clients and staff in appropriate health and hygiene methods, "as needed." This includes, but is not limited to, training of direct care staff in the identification or detection of signs and symptoms of illness or dysfunction. Yet, over two-thirds of the consultant pharmacists do not provide education or training for either patients (73 percent) or their families or guardians (70 percent). And, nearly half the consultant pharmacists do not provide drug education for nurse aides (48 percent) or medication aides (50 percent).

The law and regulations do not specifically require that such training include consultant pharmacist training to identify possible symptoms of contraindications, adverse reactions, or inappropriate responses to medications. However, it appears that such training would be an integral response to the health needs of nursing home patients. Aides should routinely be aware of the significance of patient complaints which may indicate potential medication problems. Patients complaining of light-headedness, dizziness, fainting, or acute weakness should signal the need for increased vigilance, not only for falls, but also for medication side effects. Such complaints could alert the pharmacist and nursing staff to the potential need for lab work, which could indicate drug-drug and drug-diet interactions.

While most pharmacists are familiar with their enhanced responsibilities, significant numbers voice strong concerns about limitations on their professional authority to enforce OBRA drug-related provisions.

As required, nursing facilities employ consultant pharmacists to conduct monthly reviews of each patient's drug regimen to ensure that the prescription drugs ordered for that individual are appropriate based on the OBRA 1987 guidelines. These consultant pharmacists understand that they are 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, and 3) to offer advice and instruction in all other areas of pharmacy services.

Pharmacists also realize they should report any concerns they may have about a resident's medication regimen to the attending physician or director of nursing. Further, they know

that OBRA 1990 identifies pharmacists as key health care professionals with a potential role in improving therapeutic outcomes for Medicaid nursing home residents. However, 32 percent of consultant pharmacists report they lack the authority to ensure either a facility's or physician's adherence to the OBRA drug-related provisions.

As consultants, pharmacists can make recommendations and attempt persuasion to change, but they cannot force change. More specific indicators of lack of enforcement authority include 42 percent of the pharmacists saying they are unable to control the medications ordered and dispensed in the nursing home; 27 percent saying they cannot ensure the nursing staff appropriately monitor the clinical effects of medications on residents' physical, mental, or emotional condition; and 24 percent saying they cannot guarantee the nursing staff will properly administer medications ordered. (See Appendix B, table 12.)

It is important to note that, notwithstanding their lack of authority to ensure appropriate medication regimens, most consultant pharmacists (84-90 percent) do not feel the statutory definition of their roles or their dual responsibilities to both nursing facilities and patients inhibit their ability to conduct appropriate medication reviews. This is borne out by the fact that all consultant pharmacists report they routinely conduct the required monthly drug regimen reviews for nursing home patients, and at least 75 percent say they perform a review when changes occur either to the physicians' orders or to the resident's plan of care. Nearly 93 percent of the consultant pharmacists indicate they routinely monitor each resident's medication regimen to ensure it maintains or improves the patient's functioning. Further, 95 percent of the consultant pharmacists perform the drug regimen review for a particular patient at least once a month with 31 percent of the consultant pharmacists visiting the nursing home weekly or more often.

RECOMMENDATIONS

This report shares information concerning drug usage in nursing homes from the perspective of a nationally representative sample of consultant pharmacists. Pharmacists expressed concerns about their inability to always perform quality medication reviews, the role of the physician and nursing staff in appropriate medication usage by patients, and the problems of potentially inappropriate medication usage or maintenance. Collectively with the two other reports of this inspection, these concerns show a need for improvement and underscore the importance of strengthening the medication reviews and improving medication prescribing, administration, and monitoring practices in nursing homes.

These concerns and those addressed in our first report, "An Introduction Based on Texas" (OEI-06-96-00080), indicate that HCFA should continue to work with the States and other responsible entities to improve and enforce existing requirements for more effective medication reviews for patients 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

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 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).

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 Rollinger, 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. Fanale, R. H., et al. "The Nursing Home Medical Director," *Journal of the American Geriatrics Society*, 1989, 37(4), pp. 371-373.

14. The Merck Manual, 15th edition, fourth printing.
15. Government regulation and policies of third-party payors (insurance companies) have a direct impact on utilization, perhaps mostly by decreasing the number and types of laboratory tests routinely conducted in nursing homes. Medicare has changed its policy for payment of laboratory tests (i.e., no more orders for tests, especially multiple tests, without good clinical indications). Thus, one effect of this new policy may be less lab testing, particularly for those tests which cover a variety of possible physical effects of medication (i.e., Super Chemistry).
16. According to research, there are at least four patterns of constipation found in infirm elderly nursing home patients which may often be due to secondary causes, such as physical immobility and medications (e.g., antidepressants and neuroleptics with anticholinergic properties, calcium channel blockers, iron supplements, and narcotics).
17. Elderly patients have an increased risk for falling when they experience a combination of any of the following:
 - 1) dementia, especially more advanced stages;
 - 2) orthostasis, a fall in systolic blood pressure, may be enhanced by certain antihypertensives and psychotropics as well as certain physical difficulties related to either urination or digestion;
 - 3) arthritis, particularly when the patient has limited mobility, may increase a patient's tendency to fall or to experience confusion when certain narcotic analgesics are used, usually inappropriately, for the pain;
 - 4) incontinence of urine or bowel, past stroke, or abnormal balance or gait, seizures;
 - 5) age-related decreases in sight, hearing, reaction time, sensory awareness or the use of anticonvulsants which may increase the possibility of falls for ambulatory patients;
 - 6) metabolic drug related causes include uncorrected hypothyroidism, hypoglycemia (insulin and oral antidiabetics), anemia (NSAIDS), low serum sodium and potassium, and dehydration (diuretics); and
 - 7) the inability to recognize environmental risks (e.g., unlocked bed wheels).

Also, some of the listed ailments or medications have their own potential for causing physical, mental, and emotional side effects for elderly persons.

18. Both The MERCK Manual of Diagnosis and Therapy and the AARP Prescription Drug Handbook provide the most common reasons for usage and concerns related to the usage of these drugs:

Antipsychotics ("major" tranquilizers also called neuroleptics)

Are used to treat a variety of very severe emotional disorders, including severe anxiety, agitation, or psychosis. They should not be used to treat simple anxiety. Low doses of some of these may also be used to treat nausea and vomiting. The principle restriction while taking these drugs is related to the taking of any other drugs, including over-the-counter ones, because these drugs can negatively interact with blood pressure medication, antidepressants, antihistamines, barbiturates, narcotics, tranquilizers, cimetidine (medicine for ulcers), and antibiotics. Further, these drugs may disturb the ability of a patient's body to regulate its temperature.

The most common side effects are sleepiness, sudden faintness or falling when getting up from a reclining or sitting position, muscle stiffness, and slowness of movement (each of which may be treated symptomatically by other medications which may negatively interact with antipsychotics). Certain examples should clearly be avoided for medical reasons such as thioridazine in patients with heart disease. Elderly patients who use these drugs are more prone to extrapyramidal side effects, tardive dyskinesia, and hypotension. Occurrences of other rare side effects can also be increased in the elderly (e.g., leukopenia, skin pigmentation).

Antianxiety agents ("minor" tranquilizers also called anxiolytics)

Anxiety neurosis is a neurotic disorder characterized by chronic, unrealistic anxiety often punctuated by acute attacks of anxiety or panic. It afflicts only 5 percent of the population, is characteristically among young adults, and affects women twice as often as men. Anxiety symptoms often become less severe and troublesome with middle age. The risk is that many elderly persons being treated for anxiety may not actually be suffering the illness itself.

Both physiologic and psychologic facts cause anxiety neurosis, and there is evidence that a genetic propensity may also exist. Physical examinations and laboratory studies usually can establish whether the patient is truly suffering anxiety or another illness which may manifest itself with symptoms similar to those of anxiety (e.g., Graves' disease, myocardial infarction, depression).

Benzodiazepines have largely supplanted other antianxiety drugs, including the barbiturates, meprobamate, and hydroxyzine. While phenothiazines (e.g., thioridazine) are occasionally used as antianxiety agents, their side effects make them ill-suited for ambulatory patients without marked anxiety, or for patients who do not respond or tend to become dependent with the use of benzodiazepines. [The degree of central nervous system depression produced by most anxiolytics is dose-dependent and can be severe. Further, these drugs tend to have a long half-life, and for some of the drugs in this category, half-lives increase considerably with age (four- to sixfold at age 80).] In the elderly, these drugs are often associated with over sedation, ataxia, confusion, reduced energy levels, and paradoxical excitement and delirium. Physiologic changes common to elderly persons may explain any unusual responses to the drugs. These drugs can actually worsen the conditions of patients suffering dementia or depression and, occasionally, induce florid delirium. In the elderly, these drugs should be used for short-term treatment only.

Sedatives/Hypnotics

These terms, as well as "antianxiety agent," "minor tranquilizer," and "anxiolytic" are ambiguous and often used interchangeably. A single one of these drugs is frequently useful in more than one therapeutic category, depending on the dosage. All available hypnotics involve some risk of overdose, habituation, over-tolerance, and addiction, as well as withdrawal symptoms that can include a temporary recurrence of sleeplessness. Ambulatory patients given these drugs should avoid activities requiring mental alertness, judgment, and physical coordination. They should particularly be used with extreme caution in patients with severe pulmonary insufficiency. The elderly may exhibit restlessness, excitement, or exacerbations of symptoms of organic brain disorders. Serum levels should routinely be checked for appropriate dosage levels when such symptoms are exhibited.

19. Weekly Report for Week Ending January 17, 1997, Health Care Financing Administration, Health Standards and Quality Bureau.
20. Ruegg et al presents three main types of depressive disorders in the elderly. These include:

- 1) the patient's presentation of multiple somatic complaints (headache, gastrointestinal upset, fatigue) which, in effect, "mask" or hide the presence of depressive symptoms;
 - 2) the patient complains of difficulty concentrating or remembering, and withdraws from the environment, falsely mimicking dementia; and
 - 3) the patient experiences some form of delusion. (It should be noted that there are also some forms of medical illness with symptoms mimicking a delusional depression such as a tumor or stroke or Alzheimer's disease.)
21. Chrischilles E., D. Foley, R. Wallace, J. Lemke, T. Semla, J. Hanlon, et al. "Use of Medications by Persons 65 and Over: Data from the Established Populations for Epidemiologic Studies of the Elderly." *Journal of Gerontology*, 1992; 47:M137-44.
22. Telephone conversations with Tom Clark, Director of Professional Affairs, subsequent to other conversations with Janice L. Feinberg, Director of Research and Education Foundation, both with the American Society of Consultant Pharmacists.

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 Rollingher, 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

Consultant Pharmacists' Assessments of Medication Problems in Nursing Homes (Weighted Data)

Table 1: Concerns about Residents Using Certain Medications				
Medication Type	FREQUENCY OF OCCURRENCE (During Six-Month Period Prior to Survey)			
	% Often	% Sometimes	% Rarely	% Never
antibiotics or anti-infectives	3.2	35.8	48.4	12.6
anesthetics	0.1	0.8	12.2	86.9
antipsychotics	13.3	53.3	25.8	7.6
antidepressants	6.9	31.4	47.7	14.0
anxiolytics	14.6	46.0	32.4	7.0
diuretic medications	2.6	26.3	48.8	22.2
narcotics	6.5	39.3	35.8	18.4
non-steroid anti-inflammatory	6.7	40.7	41.0	11.6
sedatives or hypnotics	12.3	49.5	28.5	9.6
steroids	2.6	11.7	53.3	32.3
gastrointestinals	3.6	32.6	46.2	17.6
ACE inhibitors	2.7	22.6	54.3	20.4
calcium channel blockers	1.1	18.5	58.9	21.5
H2 antagonists	17.7	47.6	26.8	7.9
digoxin	3.5	36.5	49.2	10.8
Source: Q30a-Q30o				

Table 2: Appropriateness of Prescribed Medication				
Problem Encountered	FREQUENCY OF OCCURRENCE			
	% Often	% Sometimes	% Rarely	% Never
medication contraindicated by diagnosis or disease	1.7	24.2	66.7	7.5
“as needed” medications administered too long	7.1	54.2	34.6	4.1
unauthorized medication with no signed orders	0.7	7.6	41.0	50.7
continuous use of sleeping medication for too long	26.5	49.6	22.1	2.1
use of antipsychotic w/o diagnosis	6.0	38.6	42.7	12.7
use of antidepressant w/o diagnosis	4.3	28.3	55.6	11.8
overutilization	9.5	52.2	33.8	4.5
underutilization	0.2	26.0	61.1	12.7
use of more than one medication in same drug	4.2	35.9	53.9	6.0

Source: Q311, Q31n-Q31u

Table 3: Number of Physicians Inappropriately Prescribing Medications					
Medication Type	% None	% Few	% Some	% Most	% All
Antipsychotics	45.8	41.5	10.1	1.9	0.7
Anxiolytics	43.8	37.6	16.0	2.6	0.0
Antidepressants	57.2	28.6	8.7	4.1	1.5
Sedatives or Hypnotics	37.8	41.9	17.0	2.6	0.7

Source: Q12a-Q12d

Table 4: Why Doctors Don't Limit Inappropriate Medications for the Elderly	
Reason	Percent Pharmacist Indicating
Lack of training	14.9%
Lack of knowledge	21.0%
Indifference	20.5%
Pressure to continue medication from:	
▶ Family/guardian	27.8%
▶ Resident	23.6%
▶ Facility staff	14.3%

Source: Q19

Table 5: Administration of Medications				
Problem Encountered	FREQUENCY OF OCCURRENCE			
	% Often	% Sometimes	% Rarely	% Never
incorrect dosage	2.2	26.5	37.1	3.4
not optimal duration	2.0	44.4	44.1	8.7
not optimal dosage	3.9	48.8	42.2	5.1
administered at incorrect time	11.4	47.6	36.9	4.1
administered to wrong resident	0.0	4.4	71.2	24.3
inappropriate dosage alteration (crush/no crush, dilution, etc.)	5.0	35.0	51.3	8.7
incorrect route of administration	0.1	8.0	59.1	32.8
wrong medication Administered	0.0	10.9	76.5	12.6

Source: Q31a-Q31g

Table 6: Monitoring of Medication Usage				
Problem Encountered	FREQUENCY OF OCCURRENCE			
	% Often	% Sometimes	% Rarely	% Never
failure to chart use	11.0	47.7	34.7	6.6
lack of dosage adjustment for renal/hepatic function	6.0	44.2	40.2	9.6
inappropriate for use by elderly	4.1	41.6	44.6	9.7
duplicate prescriptions	0.9	28.1	55.1	15.4
medication/medication interaction	3.6	53.0	38.7	4.7
medication/diet interaction	1.8	32.6	57.3	8.3
medication/gender interaction	0.0	4.3	47.8	47.9
contraindicated by resident's allergy history	0.8	19.7	63.8	15.7
lack of lab testing to ensure continued need	8.8	51.7	35.0	4.5
lack of monitoring for efficacy and side effects	11.0	38.6	36.2	14.2
lack of lab testing for routine, on-going monitoring of toxics	10.2	40.8	43.2	5.8
lack of physical assessment for continued need or appropriateness of dosage	9.1	37.5	44.3	9.1
lack of physical assessment for routine, on- going monitoring of certain medications	10.0	32.7	48.0	9.3

Source: Qf31-Qr31

Table 7: Doctors Routinely Seeking Lowest Effective Dose for Select Drug Classes				
	Antipsychotics	Anxiolytics	Sedatives/ Hypnotics	Antidepressants
Number of doctors routinely trying for lowest effective dose				
▶ All	25.5%	19.8%	21.9%	17.0%
▶ Most	45.8%	42.8%	41.4%	24.9%
▶ Some	18.6%	23.6%	15.6%	15.7%
▶ Few	8.7%	12.2%	19.1%	26.3%
▶ None	1.4%	1.6%	1.9%	16.1%

Source: Q14

Table 8: Adverse Medication Reactions				
Problem Created	FREQUENCY OF OCCURRENCE			
	% Often	% Sometimes	% Rarely	% Never
contributed to urinary incontinence	0.9	25.3	56.1	17.7
contributed to depression	1.1	38.1	50.4	10.4
contributed to delirium	0.9	39.9	45.9	13.3
contributed to falls	6.1	60.2	27.1	6.7
contributed to constipation	16.6	64.5	15.4	2.8

Source: Q31h-Q31m

Table 9: Quality Assurance and Quality Control Issues

Problem Encountered	FREQUENCY OF OCCURRENCE			
	% Often	% Sometimes	% Rarely	% Never
medication order not on MAR	0.2	17.3	62.6	19.9
medication listed on MAR w/o order	0.1	6.7	47.8	45.4
MAR not updated to reflect new dose or schedule	2.1	27.2	54.6	16.0
order sheets not current or correct when signed by MD	4.6	22.0	54.5	18.8
lack specific directions for usage	11.6	48.7	34.8	4.9
order incomplete	5.8	46.5	40.2	7.5
medications not provided for periods away from nursing home	0.2	2.6	49.1	48.1
theft of medications	0.1	5.1	49.1	45.8
misplacement of medications	0.7	21.6	62.9	14.8
medications found in trash can in resident's room	0.0	3.3	31.8	64.9
medications administered by inappropriate or unauthorized personnel	0.0	1.5	15.2	83.3
medications administered in disregard of stop orders	0.3	17.0	60.3	22.4
clinical abuse or misuse	0.0	4.6	40.6	54.8

Source: Q311-Q319, Qa31-Qe31

Table 10: Barriers to Including Non-Prescribed Medications in Review of Residents' Medication Regimens

Possible Barriers	% True	% False
Collecting data directly from residents or their guardians is too labor intensive	63.9	36.1
Facility contract does not require pharmacist's review of non-prescribed OTC medications	20.8	79.2
Records of non-prescribed OTC medications not available	34.1	65.9
Records of non-prescribed OTC medications insufficient	39.7	60.3
Non-prescribed medications not included in resident's plan of care	61.6	38.4
Non-prescribed medications not part of resident's assessment	43.3	56.7
Non-prescribed medications not included in resident's permanent medical record	48.8	51.2
Facility staff do not routinely inspect residents' rooms for non-prescribed medications	12.3	87.7

Source: Q25a-Q25h

Table 11: Policy Barriers to Appropriate Reviews of Medication Regimens		
Possible Policy Barriers	% True	% False
No clearly defined responsibilities for pharmacists performing services in nursing facilities	10.2	89.8
No clear separation between responsibilities to the nursing home and to the residents	11.6	88.4
Primarily responsible to nursing home rather than to resident	15.7	84.3
Lack of pharmacists' enforcement authority to ensure facilities' adherence to OBRA	32.1	67.9

Source: Q29a,j,k,p

Table 12: Nursing home and Other Management Issues as Barriers to Appropriate Reviews of Medication Regimens		
Possible Management Issues as Barriers	% True	% False
No control over medications ordered and dispensed in nursing home	42.4	57.6
Insufficient access to records maintained by nursing home, e.g. assessment, plan of care	11.8	88.2
No authority over nursing staff to ensure medications are administered as ordered	23.7	76.3
No authority over nursing staff to ensure medically appropriate monitoring of resident's physical condition as related to drug regimen	27.3	72.7
No means of ensuring resident's compliance with drug regimen	17.4	82.6
No authority over dispensing pharmacy	14.7	85.3

Source: Q29d,g,h,i,e,f

Table 13: Professional Authority Issues as Barriers to Appropriate Reviews of Medication Regimens		
Possible Professional Barriers	% True	% False
Lack of authority to modify drug regimen	58.6	41.4
Lack of authority to order lab tests to ensure appropriateness of drug regimen	65.5	34.5
Insufficient authority to ensure doctors appropriately prescribe residents' medications	61.6	38.4
Doctors not required to respond to pharmacists' concerns	54.4	45.6
Doctors rejection of pharmacists' recommendations	46.8	53.2

Source: Q29b,c,l,m,n

APPENDIX C

Additional Pharmacist Survey Weighted Data

Table 1: Routine Performance of Other Drug-Related Functions		
Consultant Pharmacist Functions	% Yes	% No
Ensure MAR are complete and orderly	93.7	6.3
Maintain records for medication receipt, administration, and destruction	84.1	15.9
Monitor medication records to ensure maintenance or improvement of resident's functioning	92.9	7.1
Monitor medications for expiration, proper storage, or packaging integrity	96.0	4.0
Preparation of medication dispensing mechanisms, e.g. cart	67.2	32.8
Periodically observe/evaluate medication passes to ensure accuracy of administration	85.2	14.8

Source: Q10e.p-t

Table 2: Frequency of Routine Performance of Drug Education/Training and Committee Participation		
	% Yes	% No
Drug education/training of:		
▶ nursing staff	93.0	7.0
▶ nurse aides	52.0	48.0
▶ medication aides	49.8	50.2
▶ families/guardians	30.1	69.9
▶ residents	27.1	72.9
Participation in committees for:		
▶ pharmacy and therapy	73.6	26.4
▶ quality assurance	86.5	13.5
▶ infection control	67.3	32.7
▶ care planning	10.9	89.1

Source: Q10g-k,l-o

Table 3: Difficulty in Obtaining Specific Patient-Related Records		
Patient Documents or Records	% Yes	% No
Doctors' orders	6.0	94.0
Doctors' progress notes	12.7	87.3
Nurses' progress notes	9.1	90.8
Resident's assessment	11.0	89.0
Resident's diagnosis(es)	34.7	65.3
Resident's plan of care	3.4	96.6
Lab reports	32.8	67.2
Resident's nutritional plan needs	6.5	93.5
Incident/accident reports	19.8	80.2
Medication administration records	11.0	89.0
Hospital discharge summary	25.5	74.5
Specialists' Notes (PT, OT, ST, etc.)	8.8	91.2
Transfer reports	20.4	79.6
Hospital/operation reports	30.1	69.9

Source: Q28a-n

Table 4: Routine Contacts for Medication Regimen Problems		
Who Contacted	% Yes	% No
Medical Director	43.7	56.3
Director of Nurses	93.7	6.2
RNs/LVNs/PNs	96.4	3.6
Resident	12.2	87.8
Resident's family/guardian	5.2	94.8
Resident's personal doctor	87.7	11.5
Personal doctor's PA/NP	54.9	45.0
Appropriate nurse aide	17.8	82.2
State certification agency	7.7	92.3
Dietician	42.5	57.5
Therapist (e.g. occupational, physical, speech)	24.8	75.2

Source: Q41a-k

Table 5: Frequency of Contact with Residents					
	Always	Mostly	Sometimes	Rarely	Never
Routinely meet with resident or family after medication review	1.6	0.6	15.9	44.9	37.0
Routinely ask resident or family preferences in certain prescribed medications	1.1	2.6	25.6	54.2	16.4

Source: Q47,Q48

Table 6: Cooperation Between Pharmacists and Others					
Individual With Whom Consultant Pharmacist Communicates	Extent of Cooperation				
	% Very Good	% Good	% Fair	% Poor	% No Contact
Nursing home Administrator	51.6	31.1	8.9	1.7	6.7
Medical Director for Facility	29.2	42.3	20.0	2.2	6.3
Director of Nursing for Facility	73.4	21.1	2.3	1.7	1.5
Patient's Personal Physician	12.6	44.5	35.7	3.8	3.5
Immediate Nursing Staff (RN, LVN, PN)	60.6	33.5	5.0	0.9	0.0
Nurse Aides	21.2	23.1	6.7	1.6	47.5
Patient	11.8	19.7	9.3	1.4	57.9
Patient's Family or Guardian	10.5	17.2	7.2	1.0	64.2

Source: Q60a-h