STATE OF MAINE
118TH LEGISLATURE
FIRST REGULAR AND FIRST SPECIAL SESSIONS

Final Report of the COMMISSION TO STUDY THE USE OF PHARMACEUTICALS IN LONG-TERM CARE SETTINGS

March, 1998

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EXECUTIVE SUMMARY

The Commission to Study the Use of Pharmaceuticals in Long-Term Care Settings was created by Resolves 1997, chapter 71. Commission membership included representatives of long-term care recipients, long-term care pharmacists, long-term care pharmacy providers, a physician and a nurse with long-term care experience, 2 members of the Joint Standing Committee on Health and Human Services and one other legislator, and a pharmacist or designee from the Department of Human Services with expertise in Medicaid reimbursement. The Commission was directed to examine the use of pharmaceuticals in long-term care settings. The six topics the Commission was directed to examine and the findings and recommendations with regard to each are as follows:

- Resolve Issue #1: Examine the reimbursement formulas given to long-term care pharmacy providers including fees for service and capitation rates for services

The Commission makes no recommendations on the issue of reimbursement formulas for long-term care pharmacy providers, but asks the Legislature to consider the issues presented in the full report.

- Resolve issue #2: Examine the payment of a consultant fee to providers of long-term care pharmacy services and whether there is an inherent conflict of interest between providing consulting and dispensing services

The Commission recommends that a system of monitoring be put into place to ensure that long-term care facilities are complying with federal law by entering into appropriate contracts with consultant pharmacists. Contracts must provide for proper and adequate reimbursement for the services of the consultant pharmacist, to guard against inappropriate activity under which a pharmacy offers to provide the consulting service for unreasonably low compensation in order to obtain the dispensing services contract and make up for the losses through drug costs and filling fees.

The Commission recommends that Maine enact an anti-kickback statute similar to federal law that prohibits fraudulent business practices.

The Commission urges long-term care facilities staff and their residents to educate themselves about the qualifications and services offered by consultant pharmacists and about the potential for improved outcomes, quality assurance and decreased pharmaceuticals costs from consultant pharmacists who offer a quality of service above and beyond the minimum requirements. The Commission supports a market-driven philosophy for the provision of consultant services and encourages consultant pharmacists to offer the highest quality of services.

- Resolve Issue #3: Examine the determination of new rules pertaining to dispensing pharmaceuticals in long-term care facilities, such as minimum supply, and fees charged for the same medication dispensed in the same month

The Commission recommends that the Department of Human Services periodically review its guidelines for dispensing medications for a Medicaid resident, with consideration given for the changing needs of physicians and staff to manage acute-care residents. Those residents may have multiple changes in medication therapies over short periods of time.

The Commission recommends that long-term care facilities be made aware of problems and possible solutions to problems relating to minimum supply, and that they work with all disciplines to ensure that the most reasonable, cost-effective dispensing practices are offered and maintained.

- Resolve Issue #4: Examine conflict of interest created by concurrent ownership of long-term care facilities and of pharmacies or other related health care providers that provide services to residents

The Commission recommends that the Department of Human Services review the current prohibition against paying a filling fee to pharmacies that own and provide services to nursing homes, to determine whether the current economic situation justifies a continuation of the prohibition.

- Resolve Issue #5: Examine whether there is a practice of overprescribing in long-term care facilities

The Commission was unable to determine whether there is a practice of overprescribing in long-term care facilities in Maine. The Commission does recommend the development of pharmaceutical care guidelines for geriatric residents in long-term care facilities. Once developed, these guidelines would offer geriatric-focused clinical information, assist in providing appropriate pharmaceutical care, and recommend acceptable and unacceptable drug products by clinical indication. Such guidelines can be a valuable tool in enhancing the quality of care and improving outcomes while providing more cost-effective drug therapy.

- Resolve Issue #6: Examine whether there are potential cost savings and other benefits from more efficient patterns for stocking standard, nonchargeable medical supplies

The requirement to provide house stock items is an issue that must be enforced on the nursing home level. Long-term care pharmacy providers should be aware that these items are not billable to Medicaid residents. Private paying residents should be reminded of their right to purchase these items from a pharmacy of their choice.

INTRODUCTION

The Commission to Study the Use of Pharmaceuticals in Long-Term Care Settings was created by Resolves 1997, chapter 71. Commission membership included representatives of long-term care recipients, long-term care pharmacists, long-term care pharmacy providers, a physician and a nurse with long-term care experience, 2 members of the Joint Standing Committee on Health and Human Services and one other legislator, and a pharmacist or designee from the Department of Human Services with expertise in Medicaid reimbursement. The Commission was directed to examine the use of pharmaceuticals in long-term care settings, and to examine specifically:

- Reimbursement formulas for long-term care pharmacy providers;
- Consulting fees to providers of long-term care pharmacy services and whether a conflict of interest exists between providing consulting and dispensing pharmacy services;
- Rules for dispensing of pharmaceuticals in long-term care facilities;
- Conflict of interest created by concurrent ownership of long-term care facilities and pharmacies or other related health care providers;
- Possible overprescribing in long-term care facilities; and
- The potential for cost savings and other benefits from more efficient patterns of stocking standard, nonchargeable medical supplies.

The Commission was convened on January 5, 1998 and was asked to expedite its study and complete its work by January 23, 1998. At the first meeting of the Commission, members elected Michael J. Fiori as Commission chair.

During its two January meetings, commission members discussed the various issues listed in the Resolve creating the study. Through those discussions, members gained a greater understanding of the legal and practical considerations governing each issue and developed some specific recommendations. Following its last meeting, the Commission prepared this report that, after review be commission members, was issued in March of 1998.

This report is a summary of Commission discussions and recommendations, prepared by Michael Fiori, Commission Chair, with approval of the full Commission. Attached as appendices are supporting materials.

REIMBURSEMENT FORMULAS

- Resolve Issue #1: Examine the reimbursement formulas given to long-term care pharmacy providers including fees for service and capitation rates for services

Non-Medicaid reimbursement.

The level of pharmacy services reimbursement by third-party payors (payors other than Medicaid) is driven by the market. Generally, the third party pharmacy benefit manager "dictates" the reimbursement level to the pharmacy or pharmacist.

There is controversy in the industry over the low rates of reimbursement offered by third party plans. Prescription department margins have dropped significantly in the past 5 to 10 years, jeopardizing the sustainability of many pharmacies. As a consequence, many pharmacies have had to increase their volume of business in order to survive.

Medicaid reimbursement

Medicaid reimbursement includes a formula for reimbursement for the drugs themselves and a $3.35 filling fee. The Medicaid filling fee has not been increased in approximately 8 years.

While several Commission members agreed that the pharmacist deserved an increase in the filling fee, it is recognized that a fee increase would require approval from the Health Care Financing Administration (HCFA) if the proposed increase were "outside the prevailing market."

The State of Maine prescription filling fee/formula is currently lower than approximately half of the states.

Adding to the concern about the filling fee is the fact that Maine has recently begun deducting a 25-cent "processing fee" from the $3.35 filling fee, which nets to the pharmacy a $3.10 filling fee. The legality of this deduction is currently being challenged by at least one large chain pharmacy organization in Maine and several pharmacy associations. The federal Health Care Financing Administration has not issued a final ruling on the challenge, but has preliminarily stated that the deduction cannot be termed an "administrative fee" or other such terminology.

Differential Packaging Costs

Long-term care facilities utilize "unit-dose" packaging, usually some form of "blister-pack" packaging. This makes it possible to return unused medications for a partial credit to the Medicaid program or private paying patient. This type of packaging also improves safety and nursing home outcomes by ensuring that the proper dosage is given.

Unit-dose packaging uses more expensive material and requires more of the pharmacist's or technician's time than the traditional "bottle and vial" packaging used in retail pharmacies. The preparation of the medications involves wrapping each tablet or capsule in individual blisters, providing delivery reports, providing narcotic count sheets and breaking tablets for unusual doses. It has been estimated by several long-term care pharmacy providers that the process requires 2 to 3 times more time to prepare, but there is no consideration in the Maine program for this increased cost to the pharmacy providers. They are paid the same fee that is given for traditional retail pharmacy packaging. Some other states do have a fee differential for unit-dose packaging.

The Department of Human Services recently adopted a rule allowing for higher rates of reimbursement to a pharmacy that uses a unit-dose dispensing system that results in no return of drugs. Those pharmacies will receive a 2.5% higher rate of reimbursement as an incentive to initiate such a system and to defray the added costs. The current reimbursement cap is average wholesale price (AWP) minus 10%; under this program, the cap is AWP minus 7.5%. The Department believes that the savings to the State from not having to process returns or prepare the financial reporting will offset the added expense. Cost savings have not yet been determined for the project, which began in the spring of 1997. (See Appendix B, section 80.09-A of Chapter II of the Maine Medical Assistance Manual)

Capitation rates

Capitation rates and formulas were briefly discussed, but it was concluded that since the reimbursement is market-driven no company is now precluded from offering capitation or using capitation rates or formulas.

- **Recommendations/Considerations:** The Commission makes no recommendations on the issue of reimbursement formulas for long-term care pharmacy providers, but asks the Legislature to consider the issues presented in the discussion.

CONSULTING PHARMACISTS, FEES, POTENTIAL CONFLICTS

- Resolve issue #2: Examine the payment of a consultant fee to providers of long-term care pharmacy services and whether there is an inherent conflict of interest between providing consulting and dispensing services

Commission members decided that this issue involves 3 areas to be considered: whether there is an inherent conflict of interest when pharmacies provide both consulting and dispensing services; the reimbursement rates and practices of consultant pharmacists in Maine; and guidelines and criteria for consultant pharmacists to long-term care settings.

Federal requirements for consultant pharmacists

Federal Medicaid law requires long-term care facilities to employ the services of a licensed pharmacist to review drug regimens and perform other designated services. 42 Code of Federal Regulations, section 483.60. These consultant pharmacists practice under federal and state regulations. These regulations are fairly general in nature, but require that a pharmacist:

1) Be hired under a written contract as a consultant to the facility;
2) Perform routine inspections of the pharmaceuticals storage areas;
3) Perform drug-regimen reviews of the residents' charts;
4) Check emergency and starter dose boxes;
5) Review medication administration techniques;
6) Provide in-services, attend policy meetings, etc.; and
7) Provide written reports of their activities, findings and recommendations.

The level of service required of the consultant pharmacist is determined by the particular licensing status of the facility, e.g., skilled nursing facility, intermediate care nursing facility and boarding care.

Reimbursement to consultant pharmacists

Payment to consultant pharmacists is often negotiable, and covers 2 types of services -- the "special services" which relate to the care of an individual resident, and "routine services" relating to the facility generally, e.g. review of medication storage areas and in-service education.

Federal law requires a monthly review by a licensed pharmacist of the drug-care regimen of each patient. Maine's Medicaid reimbursement principles provide for a special services allowance of up to $2.50 per resident review per month for each review performed in addition to any pharmacist consultant fees. This "cognitive services fee" is essentially a pass-through for the nursing home in the per diem rate.

Payment for services other than the drug-regimen review is more controversial. Most larger providers of these services charge approximately a $1.00 per resident per month "consulting fee" for all other services performed.

For Medicaid residents, facilities are reimbursed a certain rate per diem for which the total care of the resident is covered. This includes dietary, social services, nursing, room rate and activities. Out of these per diem monies come reimbursement to the consultant pharmacist for services other than drug-regimen review.

In recent years, some facilities have negotiated with some pharmacies to provide the entire consultant pharmacist package, including drug-regimen review, for the $2.50 drug-regimen review special service fee. In these instances, there is no other reimbursement to the consultant pharmacist. In essence, the facility is paying no fee for routine service by the consultant pharmacist, e.g., in-service education, physical review of medication stations and med carts, and maintenance of emergency drug and starter-does kits. This allows the facility to retain more of its per diem monies to be used for other services.

This practice by both facility and pharmacy may be in violation of federal law. The federal anti-kickback law prohibits a person from offering or receiving remuneration in exchange for ordering, recommending, arranging or referring a service covered by Medicare or Medicaid. 42 USC §1320a-7b. According to a 1995 paper presented to the American Society of Consultant Pharmacists by Arthur N. Lerner, Esq, provision of consulting services to long-term care facilities at no or reduced charge in consideration for status as preferred dispensing pharmacy to inpatients of the facility could be found to violate the federal anti-kickback law.

Facilities defend the practice by stating that they are paying a $2.50 consultant pharmacist fee per resident per month and long-term care pharmacy providers use this as a competitive edge to induce contracts from facilities.

Current hourly rates for pharmacists in Maine, without benefits, range from $27 - $32 per hour. The amount of time a consultant pharmacist spends in a facility doing required work varies considerably among facilities and professionals, but 6 to 12 hours per month for a facility with 50 to 100 residents is a reasonable estimate.

In recent years, the Office of Inspector General (OIG) of the federal Department of Health and Human Services has adopted "safe harbor" regulations to further define the scope of the federal Medicare and Medicaid fraud and abuse statutes. These provisions were first published in the Federal Register on November 5, 1992 in interim final form. Since that time, there have been many business practices of pharmacists that have received increased scrutiny by federal and state watchdog agencies.

The American Society of Consultant Pharmacists has issued a "Policy Statement Regarding Inappropriate Business Practices in Long-Term Care Pharmacy" which comments on activities considered to be inappropriate and possibly illegal. Among the activities falling into this category, according to the ASCP, is "offering or providing a health facility consultant pharmacist services at no charge, below-market value or below cost in exchange for obtaining or maintaining the business of the facility. (See Appendix D)

State anti-kickback laws exist with respect to the Medicaid program in nearly every state, according to Arthur Lerner. These laws largely mirror the federal law. In addition, more states are beginning to enact anti-kickback laws with respect to non-governmental payors.

In Maine, there is no anti-kickback statute. (see Appendix H for a copy of the letter from the Department of the Attorney General)

Conflict of Interest

The question has been raised whether there is a conflict of interest when the providers of pharmacy dispensing are also the providers of consultant pharmacy services in long-term care facilities. Commission members felt that it would be unlikely for the pharmacist to control utilization of medication in a way that benefited the pharmacy, since the pharmacist does not prescribe the medication. The pharmacist dispenses orders as received from the medical practitioners.

Under the federal regulation governing drug-regimen review, 42 CFR §483.60, the consultant pharmacist is required to notify the facility, nursing staff and physician if there are any irregularities, such as drug interactions, over-utilization and insufficient lab data to justify optimal usage of medications.

In general, Commission members felt that many of the questions surrounding conflict of interest are answered when good standards of practice are adhered to. Long-term care pharmacists practice in conformity with federal and state laws and rules. Some consultant pharmacists may enjoy a competitive advantage by increasing their knowledge and skills in this specialty practice by membership and participation in organizations and associations, such as the American Society of Consultant Pharmacists. Other pharmacists may attain certification from national professional organizations as a geriatric pharmacy practitioner through further study and examination.

Recommendations/Considerations

We recommend that a system of monitoring be put into place to ensure that long-term care facilities are complying with federal law by entering into appropriate contracts with consultant pharmacists. Contracts must provide for proper and adequate reimbursement for the services of the consultant pharmacist, to guard against

inappropriate activity under which a pharmacy offers to provide the consulting service for unreasonably low compensation in order to obtain the dispensing services contract and make up for the losses through drug costs and filling fees.

We recommend that Maine enact an anti-kickback statute similar to federal law that prohibits fraudulent business practices.

We do not believe there is a need to develop requirements for the practice of consultant pharmacy beyond the current federal and state laws and rules. We urge long-term care facilities staff and their residents to educate themselves about the qualifications and services offered by consultant pharmacists and about the potential for improved outcomes, quality assurance and decreased pharmaceuticals costs from consultant pharmacists who offer a quality of service above and beyond the minimum requirements. The Commission supports a market-driven philosophy for the provision of consultant services and encourages consultant pharmacists to offer the highest quality of services.

RULES ON DISPENSING OF MEDICATION

- Resolve Issue #3: Examine the determination of new rules pertaining to dispensing pharmaceuticals in long-term care facilities, such as minimum supply, and fees charged for the same medication dispensed in the same month

The Maine Medical Assistance Manual provides rules to ensure that minimum supplies of medications are dispensed and that fees charged for the medication are appropriate. Given the fact that the characteristics and needs of nursing home residents have changed since adoption of the rules, those rules need to be reexamined and updated.

Nursing home admission criteria were modified several years ago to change the function of most facilities to care for only severely ill patients and to shift many others to boarding care facilities. Consequently, the medication need or usage profile has changed considerably. Current Medicaid rules require a minimum supply of 30 days in most cases. In the Medicare setting, particularly in rehabilitation, patients may stay 2 to 4 days or in many cases less than 30 days. To decrease waste and the effort involved in return of medication, a maximum supply of fewer than 30 days, perhaps 14, might be considered.

If the minimum supply for Medicaid residents were increased, pennies may be saved at the front end, but dollars would be wasted in the long-run because of the increase in medications that would have to be destroyed because they become out of date. USP guidelines dictate that expiration dating be 25% of the manufacturer's date on the outside of the bottle, or 6 months, whichever is less. The more medication is dispensed, the more that becomes out of date and is destroyed. Second, long-term care facilities do not have the space to store an increased supply of medication. Finally, pharmacy inventory would need to be increase to supply the excessive amounts.

Recommendations/Considerations

We recommend that the Department of Human Services periodically review its guidelines for dispensing medications for a Medicaid resident, with consideration given for the changing needs of physicians and staff to mange acute-care residents. Those residents may have multiple changes in medication therapies over short periods of time. Pharmacists should be made aware of the current guidelines and any changes to them.

We recommend that long-term care facilities be made aware of problems and possible solutions to problems relating to minimum supply, and that they work with all disciplines to ensure that the most reasonable, cost-effective dispensing practices are offered and maintained.

VERTICAL INTEGRATION AND CONFLICT OF INTEREST

- Resolve Issue #4: Examine conflict of interest created by concurrent ownership of long-term care facilities and of pharmacies or other related health care providers that provide services to residents

To protect federal programs from paying excessive amounts for services and products, federal law provides that payment may be made only for transactions that are made at "arm's length." In an attempt to advise the Department of Human Services how to comply with this requirement, the Maine Attorney General prepared a list of transactions that should not be considered arm's length. As a result of this advice, the Department does not pay a filling fee for services provided by pharmacies that also own and provide services to nursing homes (vertically integrated companies).

Commission members felt that, although there may have been problems in the past with overcharging, the current economic climate justifies the department's review of the prohibition against paying a filling fee. Presently, many pharmacy providers (hospitals, retailers, etc) have access to buying groups to strengthen their buying power The possibility that the factual situation has changed with respect to the purchasing power among groups . In the late sixties or early seventies, this was not the case and the state was instrumental in passing the law to prevent excess profits in vertically integrated companies.

Recommendations

We recommend that the Department of Human Services review the current prohibition against paying a filling fee to pharmacies that own and provide services to nursing homes, to determine whether the current situation justifies a continuation of the prohibition.

PRACTICE OF OVER-PRESCRIBING

- Resolve Issue #5: Examine whether there is a practice of overprescribing in long-term care facilities

The Commission is concerned about the potential for over-prescribing of medication, but was unable to determine whether there is such a practice in Maine. None of the materials available to the Commission during its brief study revealed evidence of this practice in Maine.

Concerns about over-prescribing and excessive length of therapy might be reduced by the use of disease state management and pharmaceutical care guidelines. These guidelines could be developed by soliciting input from physicians and others who prescribe medication, medical directors, administrators, directors of nursing, staff nurses and consultant pharmacists. Once developed, the guidelines would be implemented using a team approach to involve those who write prescriptions, consultant pharmacists and nurses.

There are several existing examples of geriatric pharmaceutical care guidelines that are being used in long-term care facilities in other states and Canada. These were briefly discussed by the Commission. It is anticipated that use of such guidelines would enhance the ability of health care practitioners to provide quality care, while reducing costs, much as the use of drug management has in hospital settings.

It was also suggested that the use of guidelines might allow drug-regimen reviews to be performed prospectively, e.g., at the time of admission, by an internal consultant pharmacist and followed up by an external consultant pharmacist at the facility. For pharmacies employing this service, efficiencies and improved outcomes could result.

Recommendations/Considerations

We recommend the development of pharmaceutical care guidelines for geriatric residents in long-term care facilities. Once developed, these guidelines would offer geriatric-focused clinical information, assist in providing appropriate pharmaceutical care, and recommend acceptable and unacceptable drug products by clinical indication. Such guidelines can be a valuable tool in enhancing the quality of care and improving outcomes while providing more cost-effective drug therapy.

STOCKING PATTERNS FOR STANDARD, NONCHARGEABLE MEDICAL SUPPLIES

- Resolve Issue #6: Examine whether there are potential cost savings and other benefits from more efficient patterns for stocking standard, nonchargeable medical supplies

Standard, nonchargeable medical supplies are those supplies not paid for separately by Medicaid. These "house stock" items are expected to be covered under the per diem rate of reimbursement to the nursing home. The Medical Assistance Manual lists the categories of items that are considered house stock, including laxatives, aspirin, cough and cold syrups, etc. (See Appendix I) Medicaid residents must receive these items at no charge.

Most facilities also have a list of "standing order" items. These items are selected products from several categories, e.g. pain medications, laxatives, antacids, that the facility may also provide to private paying patients without charge, although they are not required to do so. Private paying residents have freedom of choice to obtain these supplies from a pharmacy of their choice. Although these residents are informed of this right, they often do not exercise it.

Recommendations/Considerations

The requirement to provide house stock items is an issue that must be enforced on the nursing home level. Long-term care pharmacy providers should be aware that these items are not billable to Medicaid residents. Private paying residents should be reminded of their right to purchase these items from a pharmacy of their choice.

APPENDICES
(Available in printed report only)

A. Legislation authorizing the Commission: Resolves 1997, chapter 71

B. Excerpts from the Maine Medical Assistance Manual
- 80.07-5. Dispensing Practices
- 80.09. Reimbursement

C. Federal Regulation Regarding Drug Regimen Review by Consulting Pharmacists (42 CFR sec. 483.60)

D. American Society of Consultant Pharmacists, Policy Statement on Inappropriate Business Practices

E. Article, "Consultant Pharmacist Business Practices: Navigating for a Safe Harbor", The Consultant Pharmacist, Vol. 8, No. 2 (Feb. 1993)

F. Arthur N. Lerner, Esq., Medicare and Medicaid Safe Harbors: Fraud and Abuse Issues for Consulting Pharmacy, Paper presented by Arthur N. Lerner, Esq., to the American Society of Consultant Pharmacists Sixth Annual Conference, March 1995

G. Excerpt from the State Of Maine Department of Human Services Principles of Reimbursement for Long-term care Facilities

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APPROVED
JUN 12'97
BY GOVERNOR

CHAPTER
71
RESOLVES

STATE OF MAINE

IN THE YEAR OF OUR LORD NINETEEN HUNDRED AND NINETY-SEVEN

H.P. 122 - L.D. 146

Resolve, to Establish the Commission to Study the Use of Pharmaceuticals in Long-term Care Settings

Sec. 1. Commission established. Resolved: That the Commission to Study the Use of Pharmaceuticals in Long-term Care Settings, referred to in this resolve as the "commission," is established; and be it further

Sec. 2. Commission membership. Resolved: That the commission consists of the following 10 members:

1. One pharmacist representing long-term care pharmacy providers;

2. One long-term care pharmacist;

3. One pharmacist representing a retail pharmacy;

4. One pharmacist, or a designee, from within the Department of Human Services with expertise in Medicaid reimbursement;

5. Two members of the Joint Standing Committee on Health and Human Services and one other Legislator;

6. One member representing persons receiving long-term care;

7. One physician with experience in long-term care; and

8. One registered nurse with experience in long-term care.

The members of the commission are appointed jointly by the Governor, the President of the Senate and the Speaker of the House; and be it further

Sec. 3. Appointments; meetings. Resolved: That all appointments must be made no later than 30 days following the effective date of this resolve. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. When the appointment of all members is complete, the chair of the Legislative Council shall call and convene the first meeting of the commission within 14 days after all appointments are made. The commission shall select a chair from among its legislative members; and be it further

Sec. 4. Duties. Resolved: That the commission shall examine the use of pharmaceuticals in long-term care settings. Specifically, the commission shall examine the following:

1. The reimbursement formulas given to long-term care pharmacy providers including fees for service and capitation rates for services;

2. The payment of a consulting fee to providers of long-term care pharmacy services and whether there is an inherent conflict of interest between providing consulting and dispensing services;

3. The determination of new rules pertaining to dispensing pharmaceuticals in long-term care facilities, such as minimum supply, and fees charged for the same medication dispensed in the same month;

4. Conflict of interest created by concurrent ownership of long-term care facilities and of pharmacies or other related health care providers that provide services to residents;

5. Whether there is a practice of overprescribing in long-term care facilities; and

6. Whether there are potential cost savings and other benefits from more efficient patterns of stocking standard, nonchargeable medical supplies; and be it further

Sec. 5. Staff assistance. Resolved: That the commission shall request staff and clerical assistance from the Legislative Council; and be it further

Sec. 6. Report. Resolved: That, no later than January 1, 1998, the commission shall submit a report, together with any necessary implementing legislation, to the Joint Standing Committee on Health and Human Services with a copy to the Executive Director of the Legislative Council. If the commission requires an extension, it may apply to the Legislative Council, which may grant the extension; and be it further

Sec. 7. Reimbursement and compensation. Resolved: That the commission members who are Legislators are entitled to receive the legislative per diem, as defined in the Maine Revised Statutes, Title 3, section 2 and expenses for attendance at meetings of the commission. Other members are not entitled to compensation; and be it further

Sec. 8. Meetings. Resolved: That the commission may meet up to 3 times; and be it further

Sec. 9. Appropriation. Resolved: That the following funds are appropriated from the General Fund to carry out the purposes of this resolve.

1997-98

LEGISLATURE

Commission to Study the Use of Pharmaceuticals in Long-term Care Settings

Personal Services	$495
All Other	950
TOTAL	$1,445

Provides funds for the per diem and expenses of members of the commission who are Legislators and miscellaneous costs, including printing, of the Commission to Study the Use of Pharmaceuticals in Long-term Care Settings.

80.07-4 Weekend and Holiday Authorization Prior to Provision (cont.)

C. All non-immediate APTP requests shall be submitted to:

Drug Program Coordinator
Professional Claims Review Unit
11 State House Station/249 Western Ave.
Augusta, Maine 04333-0011
- OR -fax 287-2675

D. Only when the prescriber is unable to reach the State or the authorized agent for prior authorization, a minimum of a 72-hour supply shall be provided to the recipient except for controlled substances, brand named MAC drugs, and any drug that cannot be reimbursed under existing State and Federal Regulations.

80.07-5 Dispensing Practices

Compliance with the following dispensing policies is required:

A. Dispensing practices must be in accordance with the best medical, pharmaceutical and economical practice.

B. Generic drugs as rated A in the current edition of the FDA Orange Book must be dispensed in accordance with State law, if available at a lower cost than the brand name product, unless the practitioner writes the words "Medically Necessary" in his/her own handwriting on the face of the prescription or the prescribers order sheet for institutionalized patients. Nothing other than the prescriber's own handwritten statement is acceptable. The printed box on the form or order form that could be checked by the prescriber to indicate that a name brand is necessary is not acceptable. (See 80.09-E)

C. Drugs must be dispensed in quantities sufficient to effect optimum economy (normally not less than a one month supply nor more than a three month supply for maintenance medications for chronic illness). Pharmacists will not be reimbursed for split prescriptions. Also see 80.09-(C).

D. For the classes of maintenance therapy listed below, a minimum of one month's (thirty days) supply must be supplied except when the prescriber's written orders are to the contrary or it is the initial

80.07-5 Dispensing Practices (cont.)

filling of the prescription. Drugs in ointment or cream form must be dispensed in the largest tube available when used for maintenance therapy, except in the initial filling of the prescription.

1. Analgesics
2. Antianemia drugs
3. Anti-emetics
4. Antihistamines
5. Barbiturates
6. Cardiovascular drugs
7. Dermatologicals
8. Diuretics
9. Hormones
10. Hypnotics
11. Psychotherapeutic agents
12. Sedatives
13. Spasmolytics
14. Sulfonamides
15. Hypertensive drugs
16. Tranquilizers
17. Drugs for Parkinson's disease
18. Anti-epileptic drugs
19. Peripheral vasodilators
20. Antiarthritic drugs

80.07-5 Dispensing Practices (cont.)

E. All prescriptions must be dispensed within thirty days of the date prescribed.

F. Payment for medications dispensed in quantities in lesser or greater amounts than therapeutically reasonable may be withheld pending contact with the prescriber to determine justification for the amount.

G. All prenatal vitamins must be dispensed in quantities of one hundred with no more than three refills.

H. Aspirin and acetaminophen must be dispensed in quantities of 1000 only.

Effective 3/15/96

I. Pharmacies Affiliated with Hospitals, Boarding Homes and/or Nursing Homes.

Effective 3/15/96

A pharmacy affiliated through common ownership or control with a hospital, boarding home and / or nursing home is allowed to dispense covered Medicaid prescription drugs t o Medicaid recipients in that facility. The drugs must be dispensed by a registered pharmacist, according to dispensing regulations. Drugs are to be billed in a manner consistent with the Department's billing guidelines and drug claim processing system (see Section 80.09) without professional fee.

Effective 3/15/96

J. Dispensing Practitioners

Practitioners who have been authorized to dispense drugs for Medicaid patients shall not receive a dispensing fee, but will be allowed to charge the co-pay amount in addition to the acquisition cost of drugs dispensed. Records of all such dispensing must be available for review and audit.

A participating pharmacist must maintain the original copy of all prescriptions for which payment from the Medical Assistance Program is requested. The original prescription shall be either a hard copy generated by a computer, written by the prescriber, or reduced to writing when received by the pharmacist by telephone. Information required by the Maine State Board of Pharmacy shall be recorded on each prescription and must include name of patient, name of drug, quantity ordered, directions, name of prescriber, date written and initials of pharmacist filling prescription. A record of each refill must be kept on the prescription or on the profile or be available on a computer.

80.09 REIMBURSEMENT (cont.)

A. The amount of payment for services requested and rendered shall be the lowest of the following:

1. The usual and customary charge or any amount the provider will accept from any other third party program or from the public in the form of discounts, special rebates, incentives, coupons, club plans or contracts with the exception of senior citizen discounts; or

Effective 3/15/96

2. The estimated acquisition cost (EAC) plus $3.35 professional fee except as stated in Section 80.07(5)(I).

Effective 3/15/96

3. The Federal Upper Limit (FUL) or the Maine maximum allowable cost (MMAC) plus $3.35 professional fee except as stated in Section 80.07(5).

4. Maximum reimbursement shall be at average wholesale price (AWP) minus seven and one-half percent (71/2%) for those pharmacies servicing nursing facilities, ICFs-MR and boarding homes for which the dispensing program bills Maine Medicaid for:

a. only the actual doses administered with one dispensing fee per drug per month; and

b. the program results in no drugs subject to return for credit as described in Section 80.09(H).

The copayment specified in Chapter II, Section 80.08 "Copayment" of the Maine Medical Assistance Manual will then be deducted from the amount reimbursed.

Effective 3/15/96

The Department will periodically publish a list of drugs and their prices covered by FUL or MMAC.

B. In accordance with Chapter I, of the Maine Medical Assistance Manual, it is the responsibility of the provider to seek payment from every other source except Low Cost Drugs for the Elderly Program (DEL).

It is the responsibility of the provider to verify a patient's eligibility for medical assistance prior to providing services by requesting the individual to present his or her Medical Eligibility Card on each occasion that a service is provided.

C. If a recipient's eligibility is due to expire within one month of the date of service, reimbursement will only be made for up to a one month's supply.

80.09 REIMBURSEMENT (cont.)

a. $3.35 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing.

b. $5.35 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyperailimentation.

c. $4.35 for compounding ointments and for solutions or lotions involving weighing one or more ingredients and mixing home intravenous (IV) solutions.

2. The ingredient cost is the sum of the cost of the defined ingredients contained in the compound drug. For any ingredients that cost twenty-five cents or less, twenty-five cents is the allowed charge.

G. Reimbursement for

Reimbursement for prenatal vitamins are for generic vitamins only. If the requesting physician wishes a particular brand, he or she must write "medically necessary" on the prescription.

All drugs dispensed to patients in nursing facilities, ICFs-MR, and boarding homes shall be dispensed in thirty-day supplies except for Schedule II narcotics not used for maintenance therapy. Schedule II items may be dispensed in lesser days supply if therapeutically and financially reasonable or to comply with the institution's stop order policies. Drugs in ointment form shall normally be dispensed in the largest size available.

1. All FULL OR PARTIAL UNIT DOSE or MODIFIED UNIT DOSE drugs except the following shall be returned to the pharmacy for credit if they are in a reusable condition.

a. Liquids and ointments, unless sealed packages are unopened,

b. Class II controlled drugs.

2. Instructions for Return

a. Institutions will complete Pharmaceutical Control Sheet (MCMA 45) columns 1 through 7.

b. Institutions will distribute copies of the completed form in the following manner.

80.09 REIMBURSEMENT (cont.)

Send green and yellow sheets with listed medication to servicing pharmacy;

Retain blue sheet for nursing home files;

Return white copy to:

Drug Program Coordinator
Professional Claims Review Unit
11 State House, Station
Augusta, Maine 04333

c. Pharmacies will calculate the unit price and total value (columns 8 and 9), total each sheet, and return the green copy to the Drug Program Coordinator at the above address. The Department will total all sheets and charge back 70% of the value, allowing the servicing pharmacy 30% for work involved.

These forms should be sent promptly and at least monthly. Medication not returned to a pharmacy for credit shall be destroyed in the nursing or boarding facility and witnessed by two persons who must then sign the MCMA 45.

80.10 BILLING INSTRUCTIONS

A. Billing must be accomplished in accordance with the Department's Billing requirements, per the "Billing Instructions for Pharmacy Services".

B. In order to receive full Medicaid reimbursement for claims submitted for a service that is defined as an exemption in Section 80.08-3 (Co-Pay Limitation), please use a "C" indicator in block 6 of the original claim form. A dash must be used to avoid keying errors (ex. 123456-C). On refill claim forms, please put a "C" after the Rx number.

[Code of Federal Regulations]
[Title 42, Volume 3, Parts 430 to end]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: **42CFR483**.60]

[Page 383-384]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SE

PART 483--REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES--Table of Contents

Subpart B--Requirements for Long Term Care Facilities

Sec. 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in Sec. 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who--

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) Drug regimen review. (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

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(e) Storage of drugs and biologicals.

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

[56 FR 48875, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

POLICY STATEMENT

AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

2300 Ninth Street South, Suite 515
Arlington, VA 22204-2397

Telephone 703/920-8492
FAX 703/486-2997

Inappropriate Business Practices

The American Society of Consultant Pharmacists believes some activities to be inappropriate and possibly illegal business practices and strongly encourages its members to avoid such arrangements in their dealings with health facilities, facility representatives and other health professionals.

Examples of inappropriate business practices include, but are not limited to:

- Paying a physician to sign a certification or a prescription;
- Offering or providing cash or goods to a health facility or its representative in exchange for favorable consideration in obtaining or maintaining the business of the facility;
- Offering or providing supplies and/or equipment to a health facility at no charge or below market value when these items are not integral elements of the medication distribution system;
- Paying rent to a health facility for space that is not used or is unusable or paying a rental rate for space that is significantly greater than the usual and customary rental rate for similar space;
- Paying a health facility or its representative a percentage of patient prescription charges or a flat fee when the facility provides no common or useful business service;
- Offering or providing a discount or direct payment to a health facility or its representative for billing, collection, and/or bad debt coverage services when such discounts or payments are significantly greater than the cost of similar services and/or the historical bad debt experience;
- Offering or providing computers, FAX machines, and/or other electronic devices to a health facility when that equipment is not an integral element in providing pharmacy and/or consultant services;
- Offering or providing a health facility consultant pharmacist services at no charge, below market value, or below cost in exchange for obtaining or maintaining the business of the facility.

THE ISSUE

Inappropriate Business Practices in Long Term Care Pharmacy

Pharmacists use a wide variety of business practices and arrangements in their dealings with nursing homes and other health care facilities and providers. The introduction of new services and systems and the increasingly competitive environment for pharmacy services to nursing homes has forced the adoption of business practices that some LTC pharmacists feel are inappropriate and other claim to be illegal.

Although various laws and regulations have been enacted to prohibit illegal business arrangements in the health care field, limited enforcement and the lack of interpretive guidelines have left pharmacists unsure of exactly what business practices are appropriate and legal.

This policy was recommended by the Society's Organizational Affairs Council which depended on member surveys and opinion questionnaires to guide development of a statement on business practices relevant to the LTC pharmacy field.

Summation

CONSULTANT PHARMACIST BUSINESS PRACTICES:

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Navigating for a Safe Harbor

SEE PGS. 140-141

Janice L. Feinberg

Federal law imposes criminal and civil penalties for fraud and abuse in the Medicare and Medicaid programs. The business practices of pharmacists, short of outright fraud, have received little scrutiny by federal or state watchdog agencies. However, the adoption of "safe harbor" regulations by the Department of Health and Human Services (DHHS), which went into effect July 29, 1991, should prompt consultant pharmacists to take another look at their business arrangements for dispensing and consulting services to nursing facilities as well as the provision of other services reimbursed under Medicare or Medicaid.

Although the "safe harbor" regulations do not expand the scope of the federal Medicare fraud and abuse statute, the publicity surrounding the new rules has caused many consultant pharmacists to scrutinize the appropriateness of various business arrangements including offering or providing supplies and/or equipment to a facility at no charge or below market value, various rental arrangements (paying rent to a facility for space that is not used or is unusable, or paying rent that is substantially more than the usual and customary rental rate for similar space); offering or providing computers, facsimile machines, or other equipment to a facility when that equipment can be used for a variety of nonpharmacy purposes, rather than only as part of a particular pharmacy service; and offering or providing a facility consultant pharmacist or other services at no charge, below market value, or below cost in exchange for obtaining or maintaining the drug dispensing business of the facility. *

Business arrangements with the pharmaceutical industry also must be scrutinized. Offering, soliciting, or receiving cash or free goods or services, such as

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computers or other equipment, items, or services, in exchange for "increasing a company's market share" in facilities served by the consultant pharmacist; some kinds of "bundling" of purchases or services; and some coupons, credits, and rebates not only do not fall within a safe harbor, but may violate federal law.

Legislative History

Section 1128B(b) of the Social Security Act[1]—the Medicare and Medicaid Antikickback Statute—provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive "remuneration" to induce business reimbursed under the Medicare or Medicaid programs. The offense is classified as a felony, punishable by fines of up to $25,000 and imprisonment for up to five years (Appendix 1).

The provisions of the statute are extremely broad. The types of remuneration specifically covered in the Act include kickbacks, bribes, and rebates made directly or indirectly, in cash or in kind. Prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for, in whole or in part, by Medicare or Medicaid.

Additionally, state law also may prohibit kickbacks and other abusive practices involving the Medicaid program and, in some cases, the general patient population. Issues of state law are independent of the federal antikickback statute and the safe harbor regulations. Conduct that is lawful under the federal antikickback statute or the safe harbor regulation may still be illegal under state law. Conversely, conduct that is lawful under state law may be illegal under federal law.[2]

TABLE 1. Safe Harbor Areas

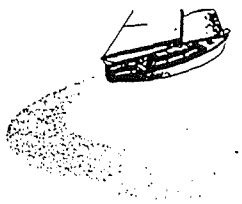
1. Investment interests
2. Space rental
3. Equipment rental
4. Personal services and management contracts
5. Sale of practice
6. Referral services
7. Warranties
8. Discounts
9. Employees
10. Group-purchasing organizations
11. Waiver of beneficiary coinsurance and deductible amounts

The breadth of the federal antikickback statute was judicially established by the Third Circuit Court of Appeals in *United States v. Greber*,[3] in which the court held that the antikickback statute applied whenever any part of the remuneration is intended to induce a referral, even when the remuneration is "also intended to compensate for professional services." In other words, if the payment was made *even in part* to induce referrals, that payment was an illegal kickback. In 1989, two additional cases confirmed this broad reading of the statute.[4,5]

The extraordinary breadth of the antikickback statute raised concern that many harmless, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.

In 1987, Congress passed the Medicare and Medicaid Patient and Program Protection Act,[6] which added two new provisions to the antikickback statute that were intended to ameliorate the harsh consequences of violating the law. The Office of Inspector General (OIG) was given authority to exclude violators from participation in the Medicare and Medicaid programs as an alternative civil remedy to criminal prosecution. In addition, the law required DHHS to promulgate regulations specifying payment practices that will not be subject to criminal prosecution or be the basis for exclusion from the Medicare or Medicaid programs under the antikickback statute. These practices are referred to as "safe harbor and are principally designed to protect arrangements and relationships that pc no danger of patient or program abuse

It is important to note that the safe harbor rules only describe what can be done without fear of prosecution. If a particular business arrangement does

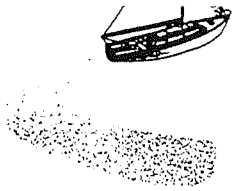


f within a safe harbor, it does not
ıean the transaction or relationship is
automatically illegal; it only means that
t legality of a particular business rela-
t ıship must be determined by compar-
ing the particular facts to the proscrip-
t is of the antikickback statute.[2]

ıcreased cost to the Medicare or
Medicaid programs and harm to benefi-
c ries are not the only criteria looked at
t letermine whether a particular busi-
ness arrangement is abusive. The court
i *Inited States v. Ruttenberg*[7] noted "the
l does not make increased cost to the
government the sole criterion of corrup-
t n. In prohibiting 'kickbacks,' Con-
g ss need not have spelled out the obvi-
ous truisms that, while unnecessary
e enditure of money . . . may exacer-
b e the result of the crime, kickback
schemes can freeze competing suppliers
from the system, can mask the possibility
c overnment price reductions, can
u direct program funds, and, when
proportional, can erect strong tempta-
t is to order more drugs and supplies
t n needed."

AFE HARBOR REGULATIONS

safe harbor regulations specify vari-
ous business or payment practices that
will not be considered "kickbacks" for
purpose of criminal prosecution or
vil sanctions under the antikickback
statute. Not every arrangement that falls
side of the safe harbor will violate the
and and abuse provisions; however,
ncreased enforcement is now expected
inst kickbacks and other questionable
ness practices that do not fall within
safe harbor regulations.



The failure to comply with a safe harbor can mean one of three things. First, it may mean that the arrangement does not fall within the proscriptions of the statute. In other words, the arrangement is not intended to induce the referral of business reimbursable under Medicare or Medicaid; therefore, there is no reason to comply with the safe harbor standards, and no risk of prosecution. At the other end of the spectrum, the arrangement could be a clear statutory violation and also not qualify for safe harbor protection. If the arrangement is obviously abusive, prosecution would be very likely.[2]

Finally, an arrangement not in compliance with a safe harbor provision may violate the antikickback statute in a less serious manner. The degree of risk of prosecution will depend on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution.[2]

During the notice and comment period before promulgation of the final safe harbor rule, numerous commenters expressed concern about the difficulty in revising a business arrangement entered into with a good-faith belief that the arrangement did not violate the statute, but which they now find does not qualify under one of the safe harbor provisions. The OIG responded that the failure of a particular business arrangement to comply with the safe harbor provisions does not determine whether the arrangement violates the statute because the regulation does not make conduct illegal. Any conduct that could be construed to be illegal after promulgation of the safe harbor rule would have been illegal at any time since the fraud and abuse law was enacted in 1977.[2] The safe harbor regulation is intended to provide a formula for avoiding risk in the future. Although diligent, good-faith efforts to restructure arrangements to comply with the safe harbor provisions would be taken into account, there is no blanket protection—even for a limited period of time—for business arrangements that do not qualify for a safe harbor.[2]

"SAFE HARBORS" ARE PRINCIPALLY DESIGNED TO PROTECT ARRANGEMENTS AND RELATIONSHIPS THAT POSE NO DANGER OF PATIENT OR PROGRAM ABUSE.

Safe Harbor Requirements

The regulation sets forth safe harbors in 11 broad areas (Table 1); safe harbors for managed care activities were recently published as an interim final regulation.[8] This article will focus on safe harbors for discounts and group purchasing organizations. The other safe harbors are briefly summarized below.

Investment Interests. By investors in a position to make or influence referrals to publicly traded corporations, the entity must have more than $50 million in assets; investment interest must be obtained through public trading on terms equally available to the public at large; the entity must not market or furnish services to such investors differently than to noninvestors; may not provide or guarantee loans to such investors if any part is used to obtain the investment interest; and return on investment must be directly proportional to the amount of the capital investment.

Where the entity possesses investment interests that are held by either active or passive investors, no more than 40% of the investors are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity; no more than 40% of the entity's gross revenue comes from referrals from, or items or services furnished by, such investors; the terms on which an investment interest is offered to such investors is no different from the terms offered to nonreferring investors and must not be related to volume of business referred or the amount of business otherwise generated from that investor to the entity; there can be no requirement that an investor make or influence referrals or otherwise generate business for the entity as a condition for remaining an investor; the entity must not market or furnish services to referring investors differently than to

noninvestors; may not provide or guarntee loans to such investors if any part s used to obtain the investment interest; and return on investment must be lirectly proportional to the amount of he capital investment.

Space and Equipment Rental. The ease agreement is set out in writing and s for at least one year; the charges are set in advance and reflect fair market alue; and, if access to the space or quipment is for periodic intervals, such intervals are set out in advance in the ease.

Personal Services and Management Contracts. The agreement is set ut in writing, specifies the services to e provided, and the term is for at least one year; if services are on a periodic or art-time basis, the agreement specifies xactly the schedule of such intervals, their precise length, and the exact charge for such intervals; and compensaion is set in advance at fair market alue. (Arrangements that are directly tied to the volume of business or amount f revenue generated receive no safe harbor protection.)

Employees. Payments in any manner o bona fide employees for the solicitaion of program business.

Waiver of Beneficiary Coinsurnce and Deductible Amounts. Hositals may waive for inpatient hospital services that Medicare pays under the rospective payment system if the hospil does not claim the amount as a bad debt or otherwise shift the burden of the reduction or waiver onto Medicare, Medaid, other payers, or individuals; and the nospital must offer the waiver or reduction without regard to the reason for

admission, length of stay, or diagnosis related group for which the claim for Medicare reimbursement is filed.

Coinsurance or deductible amounts may be waived for services that may be payable in whole or in part under part B of Medicare or Medicaid by certain eligible facilities (generally federally qualified health care centers or Public Health Service facilities).

Referral Services. The referral service does not exclude any individual who meets the qualifications for participation; fees are assessed equally on all participants and are not based on the volume or

Appendix 1. Medicare and Medicaid Fraud and Abuse Law

(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under subchapter XVIII of this chapter or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under subchapter XVIII of this chapter or a State health care program;

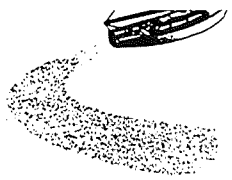
(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under subchapter XVIII of this chapter or a State health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person (which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract), and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity; and

(D) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987.



value of referrals; the referral service
ıposes no requirements on the manner
ıı which the participant provides services
to a referred person; and where the ser-
ce makes certain required disclosures
~ persons seeking a referral.

Warranties. The buyer fully reports
y price reduction obtained as part of
e warranty to DHHS or the state Med-
icaid agency; the manufacturer or suppli-
reports the price reduction, as well as
obligations to the buyer, on the
invoice or statement; and the manufac-
rer or supplier must not pay any indi-
dual or entity, other than a beneficiary,
for any expense incurred by a beneficiary
her than the cost of the item itself.

For a business arrangement to comply
with one of the safe harbors, each stan-
rd of that safe harbor provision must
met.

Discount Safe Harbor

he antikickback statute provides a statu-
ry exemption for a discount or other
reduction in price obtained by a provider
services if the reduction is properly
sclosed and appropriately reflected in
the costs claimed or charges made by the
ovider to the Medicare or Medicaid
ograms (Appendix 1). The statute's
definition of discount is very broad; the
iscount safe harbor provision, however,
much more narrowly written.

The discount safe harbor states the
rohibited "remuneration" (as used in
e antikickback statute) does not
clude a "discount" if the buyer and sell-
er comply with the applicable standards
the rule (Appendix 2).

DHHS did not propose to protect
many kinds of marketing incentive pro-
ams, such as cash rebates, free goods
or services, or redeemable coupons or credits in the safe harbor provisions.[2] The final rule, however, did protect rebate checks, redeemable coupons, and credits, subject to specific conditions.

"Discount" is defined in the safe harbor as a reduction in the amount a seller charges a buyer (directly or through a wholesaler or group purchasing organization) for a good or service based on an armslength transaction. The term discount may include a rebate check, credit, or coupon as long as the following conditions are met: (1) the instruments be redeemed only by the seller; (2) the discounts only be applied to the same good or service that was purchased or provided (e.g., a coupon or credit obtained from the purchase of one good or service cannot be used toward the purchase of a different good or service); (3) these forms of discounts must be fully and accurately reported; and (4) such discounts must be given at the time the good or service was purchased or provided.

The reporting of credits presents an unusual situation because the monetary value of the credit only applies to future purchases. To comply with the discount safe harbor provision, the buyer must report the credit on the applicable cost report or claim form covering the goods or services for which the credit is being used.[2]

Within the safe harbor, the term discount does not include:

1. Cash payments;
2. Furnishing one good or service without charge or at discount in exchange for any agreement to buy a different good or service;
3. Reduction in price applicable to one payer but not to Medicare or Medicaid;
4. Reduction in price offered to a beneficiary (such as routine reduction or waiver of coinsurance or deductible);
5. Warranties;
6. Services provided in accordance with personal or management services contract; or
7. Other remuneration in cash or in kind not explicitly described above.

"Bundling" and Free Goods. Bundling of services, such as providing consultant services, training of nursing staff, facsimile machines, medication or treatment carts, forms, or other equipment or items at no charge or at a reduced price in connection with obtaining the prescription business of a facility, is a business arrangement that risks scrutiny by the OIG and may be subject to civil or criminal enforcement action. The same analysis of bundling and the provision of free goods or services also can be applied to business arrangements between consultant pharmacists and the pharmaceutical industry.

The OIG, in its response to the question of "bundling" of goods or services, indicated:

"Congress did not intend to include within [the discount exemption] the practice of a seller giving away, or reducing the price of, one good in connection with the purchase of a different good. Such arrangements, for the most part, do not represent price reductions where the value of the goods received can be measured and fully reported to the Medicare and Medicaid programs. Although there are many instances

Appendix 2. Discount Safe Harbor Provision

(h) Discounts. As used in section 1128B of the Act, "remuneration" does not include a discount, as defined in paragraph (h)(3) of this section, on a good or service received by a buyer, which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program, from a seller as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section:

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within each category—

(i) If the buyer is an entity which reports its costs on a cost report required by the Department or State agency, it must comply with all of the following four standards:

(A) the discount must be earned based on purchases of the same good or service bought within a single fiscal year of the buyer;

(B) the buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) the buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section.

(ii) If the buyer is an entity which is a health maintenance organization or competitive medical plan acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(iii) If the buyer is not an entity described in paragraphs (h)(1)(i) or (h)(1)(ii) of this section, it must comply with all of the following three standards:

(A) the discount must be made at the time of the original sale of the good or service;

(B) where an the item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and

(C) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section.

(2) With respect to either of the following two categories of buyers, the seller must comply with all the applicable standards within each category—

(i) If the buyer is an entity described in paragraph (h)(1)(ii) of this section, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is any other individual or entity, the seller must comply with either of the following two standards:

(A) where a discount is required to be reported to the Department or a State agency under paragraph (h)(i) of this section, the seller must fully and accurately report such discount on the invoice or statement submitted to the buyer, and inform the buyer of its obligations to report such discount; or

(B) where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice or statement submitted to the buyer, inform the buyer of its obligations under paragraph (h)(1) of this section and, when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied.

(3) For purposes of this paragraph, the term discount means a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or a group purchasing organization) for a good or service based on an arms length transaction. The term discount may include a rebate check, credit, or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished. The term discount does not include—

(i) Cash payment;

(ii) Furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service;

(iii) A reduction in price applicable to one payer but not to Medicare or a State health care program;

(iv) A reduction in price offered to a beneficiary (such as a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary);

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration in cash or in kind not explicitly described in this paragraph.

References: 1. Feighner JP, Cohn JB. Analysis of individual symptoms in generalized anxiety—a pooled, multistudy, double-blind evaluation of buspirone. *Neuropsychobiology* 1989;21:124-130. 2. Newton RE, Marunycz JD, Alderdice MT, Napoliello MJ. Review of the side-effect profile of buspirone. *Am J Med* 1986;80(suppl 3B):17-21.

where these practices are cost effective arrangements that benefit the health care provider, there is enormous potential for abuse.

"Even where the particular item that is being given away may result in a more effective means of delivering the supplies to the health care provider, these types of 'discounts' cause problems because they often shift costs among reimbursement systems or distort the true costs of all the items. As a result, it may be difficult for the Medicare and Medicaid programs to determine the proper reimbursement levels. . . . For these reasons, we decline to broaden the scope of this provision to include discounts on bundled goods and have clarified the definition of the term 'discount' to specifically exclude such arrangements."[2]

For purchasing practices involving the free provision of items or services, OIG will examine the surrounding circumstances to determine the desirability of prosecuting the arrangement. Examples of potential factors that may be considered include: (1) the amount of the benefit that was reported and passed along to the Medicare or Medicaid program; (2) whether the good is separately reimbursable; and (3) the intent behind the arrangement.[2]

A related issue is the practice of giving away free computers which, in some instances, can only be used as part of a particular service that is being provided (e.g., printing out results of laboratory tests). When the computer that is given away is a regular personal computer that can be used for a variety of purposes, the computer has a definite value and, depending on the circumstances, may well constitute an illegal inducement.[2]

Discount Safe Harbor—Buyer Standards

For those items that qualify as discounts, the regulations create a safe harbor for cost-based providers, charge-based providers, and certain health-maintenance organizations (HMOs) and competitive medical plans (CMPs). Buyers must comply with all applicable standards within each category.

In general, a risk contract CMP or HMO need not report discounts except as otherwise required under its risk contract.

Cost-Based Providers. If a buyer reports its costs on a cost report required by Medicare or Medicaid (e.g., hospitals):

1. The discount must be earned based on purchases of the same good or service bought within a single fiscal year;
2. The buyer must claim the benefit of the discount in the fiscal year in which the discount was earned or the following year (for end-of-year discounts);
3. The buyer must fully and accurately report the discount in the applicable cost report; and
4. On request by the Secretary of DHHS or a state agency, the buyer must provide certain information provided by seller.

Charge-Based Providers. If the provider is paid on the basis of charges or acquisition costs (e.g., pharmacies), it must comply with all of the following three standards:

1. The discount must be made at the time of the original sale of the good or service;
2. If the item or service is separately claimed for payment by Medicare or Medicaid (i.e., drugs), the buyer must fully and accurately report the discount on that item or service; and
3. On request by the Secretary of DHHS or a state agency, the buyer must provide certain information provided by the seller.

For cost-based providers, the safe harbor regulation does not require the provider to reduce its cost separately by the amount of the discount because the statutory cost reporting requirements accomplish this statutory purpose by requiring the amount of the discount be "appropriately reflected in the costs claimed"; the discount is thus passed along to the Medicare or Medicaid programs. However, charge-based providers are required to report accurately and fully the discount for items and services that are separately claimed as a line item for payment by Medicare or Medicaid.

It should be noted that where items and services are paid on the basis of charges or acquisition costs, the discount safe harbor provision does not include end-of-year discounts. This is because it is not possible to determine retrospectively how much end-of-year discounts reduce the price of the goods or services previously purchased or provided. However, for cost-based providers, end-of-year calculations of discounts on purchases of the same good or service can be fully and accurately reported; thus, the discount safe harbor protects end-of-year discounts for cost-report providers.[2]

Discount Safe Harbor—Seller Standards

If the buyer is a risk contract CMP or HMO, the seller need not report the discount to the buyer. If the buyer is any other individual or entity, the seller must comply with either of the following two standards:

1. If the discount is required to be reported to Medicare or Medicaid by the buyer, the seller must fully and accurately report the discount on the invoice or statement submitted to the buyer and inform the buyer of the seller's obligation to report the discount; or
2. Where the value of the discount is not known at the time of sale (e.g., end-of-year discounts), the seller must report the existence of the discount program on the invoice, inform the buyer of the seller's obligations under this section, and when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount, identifying specific goods or services purchased to which the discount is attributed.

Discount Reporting Requirement

The fundamental test for complying with the reporting requirement of the discount safe harbor is whether the actual purchase price net of any discount is fully and accurately reported by the seller on the invoice, and by the purchaser on the claim or request for payment submitted to Medicare or Medicaid. The OIG has indicated it will not require all the information in the calculation of the discount to be noted specifically on the invoice or claim for payment; a notation may be made that the actual purchase price is "net discount."[2]

A question arises as to the interrelationship between the safe harbor provisions and reimbursement rules promulgated by the Health Care Financing Administration (HCFA). A few commenters on the safe harbor regulation suggested that if a health care provider complied with a particular safe harbor provision, then its reimbursement may be affected. OIG emphasized that nothing in the regulation changes the reimbursement rules promulgated by HCFA or a state health care program: "Clearly if a provider chooses to engage in one course of conduct in order to comply with these safe harbor provisions, such action may very well have reimbursement implications. However, such reimbursement is governed exclusively by

HCFA or State regulations, and not by this regulation."[2]

What the OIG seems to be saying is, although the discount safe harbor regulation does not change the Medicaid or Medicare reimbursement formula, the only way to comply with the safe harbor provision is to report the discount on the Medicaid or Medicare claim form.

Group Purchasing Organizations

This safe harbor applies to payments made by a vendor to a group-purchasing organization (GPO). GPO is defined as an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing Medicare or Medicaid services and who are neither wholly owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO, either directly or through another wholly-owned entity (e.g., nursing home or hospital chains).

OIG noted that Congress did not intend this exception to apply when the vendor, not the health care provider, is furnishing services and directly billing the Medicare or Medicaid programs, such as for laboratory services and durable medical equipment (DME): "A GPO acting on behalf of a group of nursing homes is not serving as a GPO when it receives a 'GPO fee' from a laboratory or DME supplier that bills Medicare or Medicaid directly."[2]

The GPO safe harbor states that "remuneration" does not include any payment by a vendor to a GPO as part of an agreement to furnish goods or services to an individual or entity as long as both of the following two standards are met:

1. The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following:

a. The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3% or less of the purchase price of the goods or services provided by that vendor.

b. If the fee paid to the GPO is not fixed at 3% or less, the agreement must specify the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where the amount may be a fixed sum or fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and GPO).

2. Where the entity which receives the good or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

The GPO provision applies only to payments made by vendors to persons authorized to act as a GPO. Payments such as discounts made by vendors to health care providers must qualify under the discount exception.

ALTHOUGH THE PROSCRIPTIONS OF THE ANTIKICKBACK STATUTE AND REQUIREMENTS OF THE SAFE HARBOR PROVISIONS MAY NOT COMPORT WITH EXISTING MARKET REALITIES, INCREASED ATTENTION TO FRAUD AND ABUSE ISSUES WILL NECESSITATE A CHANGE IN THE PREVAILING "BUSINESS AS USUAL" ATTITUDE.

Implications for Consultant Pharmacists

To date, the OIG and state law enforcement agencies have apparently paid relatively little attention to transactions between pharmacists and long-term care facilities. This may be a result of a lack of awareness of the consultant pharmacist's influence on the prescribing of drugs for nursing facility residents. The absence of vigorous enforcement may not continue; therefore, consultant pharmacists who enter into business arrangements that are covered by the antikickback statute, and who choose not to comply with the safe harbor provisions, risk scrutiny by the OIG and may be subject to civil or criminal enforcement action.

The following are examples of some

business arrangements that may raise serious concerns:

- A pharmacy provides a free facsimile machine to a nursing facility to use for the transmission of orders to the pharmacy. This practice may withstand scrutiny if the machine is used for pharmacy purposes only, has no independent value apart from the pharmacy service that is being provided, the purpose of providing the free machine is not to induce an act prohibited by the antikickback statute, and the machine is part of a package of services provided at a price that can be accurately reported to the Medicare or Medicaid programs. To ensure the facsimile machine is used for pharmacy purposes only, it should be connected to a dedicated pharmacy line or provide an audit trail of transactions.
- A pharmacy pays a nursing facility to handle billing for the pharmacy's prescription or Medicare Part B business. If the amount paid to the facility for this service exceeds its fair market value, the arrangement would be suspect as a possible kickback arrangement in violation of federal law.[9]
- A pharmacy provides consultant services (e.g., drug-regimen review, nursing in-service programs, medication-error surveys) to a nursing facility at no charge or below market value for the purpose of gaining the prescription drug business covered under Medicare or Medicaid generated by residents in the facility. Although this particular practice has not been directly addressed, the practice of tying free or below market value consultant services to a provider contract may be a violation of the antikickback statute. Pharmacies and nursing facilities would have greatly increased protection from fraud and abuse allegations if a fair market value were paid for consulting and other services.[9]
- A pharmacy provides medication carts at no charge or below market value for use at a nursing facility for delivering or administering medications to facility residents. If this activity is merely part of the quality service the pharmacy provides to fulfill its responsibility to patients, it would not be a questionable practice. Questions would arise, however, if the pharmacy's offer includes services that would normally be the responsibility of the facility itself, and is partly made to gain a foothold in the prescription drug business generated by residents in the facility. Safe harbor protection could be obtained if the equipment were rented to the facility at fair market rates for a term of not less than one year. If the pharmacy does not charge for the cart because of local custom, the fair market value of the cart should be incorporated into the overall charge.[9]
- The pharmacy receives professional services, redeemable coupons or "points," or other items free from a pharmaceutical manufacturer for meeting a specified level of purchases. The pharmacy receives a free computer for increasing a pharmaceutical manufacturer's market share of a product in the facilities served by the pharmacy. The aforementioned practices do not qualify for safe harbor protection under the discount provision. The issue in terms of legality becomes whether "perks" are considered an "inducement" to purchase drugs reimbursed by the Medicare or Medicaid programs.

The numerous and varied business arrangements between pharmacies and nursing facilities may come under increasing scrutiny since the promulgation of the final safe harbor rules. Consultant pharmacists may believe that many of these arrangements have a legitimate business purpose or promote the delivery of needed services. However, the antikickback statute specifically proscribes the giving of "rebates" as a form of remuneration to induce referrals.

In declining to create safe harbor protection for business arrangements that have a "legitimate business purpose," the OIG noted that rebates are legitimate and common business practices outside the health care services sector, yet the practice is expressly prohibited by the antikickback statute.[2]

Although the proscriptions of the antikickback statute and requirements of the safe harbor provisions may not comport with existing market realities, increased attention to fraud and abuse issues will necessitate a change in the prevailing "business as usual" attitude.

References

1. Social Security Act, 42 U.S.C. 1320a 7b(b).
2. Department of Health and Human Services, Office of Inspector General. Medicare and State health care programs: fraud and abuse; OIG anti-kickback provisions. Fed Regist 1992(July 29); 56:35952.
3. United States v. Greber, 760 F.2d 68 (3rd Cir. 1985).
4. United States v. Kats, 871 F.2d 105 (9th Cir. 1989).
5. United States v. Bay State Ambulance and Hospital Rental Service, Inc., 874 F.2d 20 (1st Cir. 1989).
6. Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93.
7. United States v. Ruttenberg, 625 F.2d 173 (7th Cir. 1980).
8. Department of Health and Human Services, Office of Inspector General. Medicare and state health care programs: fraud and abuse; safe harbors for protecting health plans. Fed Regist 1992 (Nov 5); 57:52723.
9. Lerner AN. Evaluation of law and regulations re: fraud and abuse ban on payments for referrals (part 1). Arlington, VA: American Society of Consultant Pharmacists, Special Bulletin, 1991 (Dec).

MEDICARE AND MEDICAID SAFE HARBORS: FRAUD AND ABUSE ISSUES FOR CONSULTING PHARMACY

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I. IMPROPER REMUNERATION FOR REFERRALS

A. Statutory prohibition on improper remuneration

o Federal law bars offering or receiving remuneration in exchange for ordering, recommending, arranging or referring a service covered by Medicare or Medicaid.[1] See Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b.

o Penalties include criminal sanctions, fines or debarment from Medicare and Medicaid.

o Rationale = kickbacks and other improper remuneration drive up costs, spur unnecessary utilization, and potentially compromise integrity of referral and therapeutic decisions.

o Improper "remuneration" need not be cash. It can be goods or services.

o Law violated if a purpose of the remuneration is to induce referral or ordering of service. Need not be principal purpose. Not a defense that remuneration is fair in relation to other consideration provided.

o Proposed legislation (S. 245, sponsored by Senator Cohen of Maine) would extend the provisions of section 1320a-7b to include virtually all third party health care payors, including self-insured employers offering employee health benefit plans.

B. Examples of prosecutions.

o Hospital official instrumental in hospital's award of ambulance service contract was convicted of conspiring to commit Medicare fraud. He served simultaneously as a consultant

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[1] Individual states have their own prohibitions on kickbacks and other abusive practices involving Medicaid patients, and in some cases the general patient population.

to the ambulance company, and had received cars from it. The ambulance company was also convicted. U.S. v. Bay State Ambulance and Hospital Rental Services, Inc., 874 F.2d 20 (1st Cir. 1989).

o Physician convicted of Medicare fraud for paying other physicians "interpretation fees" for monitors on patients referred to the defendant's diagnostic cardiology laboratory. Court held that, even if payments had been made for actual services, the payment was illegal kickback so long as the payment was intended, even in part, to induce referrals. U.S. v. Greber, 760 F.2d 68 (3d Cir. 1985).

o Laboratory company convicted for sending 50% of its laboratory revenues to company that referred lab specimens to it. Court held that if one purpose of payment was to induce referral, there could be violation of statute even if referral source was also being paid for drawing the specimen, transporting it, and bringing the lab results back. United States v. Kats, 871 F.2d 105 (9th Cir. 1989).

o Clinical laboratories barred from Medicare program for offering remunerative investment opportunities to physicians, where doctors told that failure to refer would be "blueprint for failure"; lab management arrangement with Smith-Kline Bioscience unlawful because it served to induce reference lab work to be referred out to SKB. Hanlester Network v. Sullivan, No. CV-92-4552-WGR (D.C. Cal. Feb. 15, 1993).

o Participation in activities that violate the anti-kickback laws could also result in liability under other federal laws. In United States v. Sims-Robertson, 1994 U.S. App. LEXIS 1146 (Jan. 18, 1994), convictions of two physicians, four pharmacists, and the owner and operator of a medical clinic were upheld by the Sixth Circuit Court of Appeals on RICO, drug conspiracy, mail fraud, illegal drug distribution, Medicaid fraud offenses. The pharmacists were also convicted of knowingly filling prescriptions that were issued outside the course of professional practice. In this case, patients of a clinic, who were primarily drug abusers or sellers complaining of back pain, would give four tubes of blood in order to get prescriptions for controlled substances, which they subsequently sold on or near the premises of the clinic. Four pharmacists at two cooperating pharmacies filled the prescriptions and billed Medicaid for both the cost of the drugs and a dispensing fee, and then paid the clinic a kickback for each prescription filled. The clinic used an unlicensed physician's assistant to "treat" the patients with the cooperation of two physicians, established a policy where all patients were given a blood test on their first visit and every six months thereafter, and arranged for the pharmacies to fill the controlled and non-controlled prescriptions.

o Failure to comply with fraud and abuse laws could also subject the health care provider to prosecution under the federal False Claims Act where a pattern of overutilization can be established. The federal government has prosecuted parties under the False Claims Act, maintaining that claims submitted by a provider are knowingly false if the provider knows that services rendered are not reasonable and necessary for the treatment of an illness or injury.

C. Commercial Litigation Arising out of Fraud and Abuse Violations.

In Vana v. Vista Hospital Systems, Inc., No. 233623 (Cal. Sup. Ct. 9/23/93), a court voided below-market rate leases between a hospital and physician tenants in hospital-controlled medical office buildings, holding that such agreements were illegal and unenforceable under federal and state health care anti-kickback laws. The court ruled that because the hospital had intentionally entered into below-market lease arrangements with the intent of inducing patient referrals to the hospital, the leases were illegal regardless of the physician's culpability. The court found, moreover, that even though the hospital had been the party that committed the violation, its new owners could void the leases.

Vana Vista and similar cases signal to individuals entering into business arrangements that it may be very difficult to enforce another party's obligations under an arrangement if it violates the fraud and abuse laws, injecting uncertainty into such arrangements, and possibly resulting in economic losses to such individuals.

Other recent cases involving private enforcement include Medical Laboratories, Inc. v. Smith-Kline Beecham Clinical Laboratories, Inc., (N.D. Ill. 1994), in which the court held that a "cooperative management agreement" between Medical laboratories and a division of International Clinical Laboratories, Inc. ("ICL"), which was later acquired by Smith-Kline Beecham Clinical Laboratories, Inc. ("Smith-Kline"), was illegal under the federal anti-kickback provisions. The Agreement provided that a division of ICL would market, manage, and operate MML's laboratory business and facilities in exchange for 90% of the revenue generated from MML's customers and territory. MML was to receive 10% of the revenue. When Smith-Kline took over ICL, it advised MML that it would not make further payments under the Agreement because it believed the Agreement could be illegal. MML sued Smith-Kline for breach of contract and sought a declaration that the Agreement did not violate the Act. The court held that under the Agreement, MML arranged for laboratory testing services to be purchased from ICL and that MML received remuneration for this "arrangement" service. According to the court, this violated the Act's

prohibition on receiving remuneration in return for arranging for the purchasing of any Medicaid-reimbursable service. The court said that it was irrelevant that a physician made the initial decision to purchase certain testing services.

C. "Safe harbor" regulations

Regulations now specify some practices that are not unlawful remuneration. 56 Fed. Reg. 35952 (July 29, 1991), codified at 42 C.F.R. §§ 1001.951 et seq. Not every arrangement outside a "safe harbor" is illegal. Increased enforcement expected against kickbacks and other questionable business transactions outside the safe harbors.

Safe harbors:

o Discounts by seller to buyer; various limits; requires disclosure by seller to buyer, and by buyer to government payor, where item is separate line item charge to government.

o Payments to bona fide employees.

o Written equipment or space rental for a term of at least a year, at fixed rate of compensation that reflects fair market value without taking into account the proximity of potential referral sources.

o Written service contract for a term of at least a year, at fixed rate of compensation that reflects fair market value, and that does not establish payment based on the volume of business.

o Investment interests, where no more than 40 percent of investors are in a position to make or influence referrals or to furnish services to the venture, where referring investors are not treated more favorably than non-referring investors, where investment return is not related to volume of business referred, and where no more than 40 percent of the venture's gross revenue comes from referrals from, or items or services furnished by, investors.

o Investments in large publicly traded companies by potential referral sources; investment must be obtained on terms equally available to the public at large; the entity may not market services to such investors differently than to non-investors, may not guarantee loans to such investors as a means of obtaining the investment, must have more than $50 million in assets, and must distribute profits based on capital investment;

o Warranties, where the buyer reports any price reduction to the Department of Health and Human Services, or the

applicable state Medicaid agency, where the manufacturer or supplier reports the price reduction as well as the buyer's obligations to the buyer, and where the manufacturer does not pay any person any amount under the warranty, except the cost of the item itself to the beneficiary;

o Copayment or deductible waivers inpatient hospital services covered on a prospective payment system basis, no safe harbor now available for copayment waivers of Part B items, or cost-reimbursed items;

o Referral services that do not exclude any individual who meets its qualifications for participation, where fees are assessed equally on all participants and are not based on the volume or value of referrals, where the service imposes no requirements on the manner in which the participant provides a service to the patient, and where the service makes certain disclosures to persons seeking referral; and

o Payments by a vendor to a group purchasing organization ("GPO"), authorized to act as an agent by entities that furnish Medicare or Medicaid covered goods or services, where the GPO has an agreement with its participants meeting specified criteria.

o Acquisition of the medical practice of a physician who will not be in position to make referrals to acquirer.

o Discounts by providers to certain managed care programs. 57 Fed. Reg. 52723 (Nov. 5, 1992).

o Increased benefits, lower copays and other incentives offered by health plans to enrollees. 57 Fed. Reg. 52723 (Nov. 5, 1992).

D. Possible new safe harbors.

New safe harbors may be issued covering:

o Investments in wholly-owned subsidiaries.

o Modifications of the safe harbors for investment interests if the entity in question serves rural areas (and receives 85% of its gross revenue from services provided in rural areas), as defined by the Office of Management and Budget and used by the Office of the Census. 58 Fed. Reg. 49008 (Sept. 21, 1993).

o Modifications of the safe harbors for investment interests for investments in ambulatory surgical centers ("ASC") for surgeon-investors in Medicare certified ASCs who refer

patients directly to the ASC and perform surgery themselves on the referred patients. 58 Fed. Reg. 49008 (Sept. 21, 1993).

o Modifications of the safe harbors for payments to investors in entities composed only of active investors in a physician group practice. 58 Fed. Reg. 49008 (Sept. 21, 1993).

o Certain practitioner recruitment payments in rural areas, for a practitioner who needs to relocate to a new geographic area and start a new practice, or a new practitioner who needs assistance in starting a practice or specialty after completing an internship or residency program. 58 Fed. Reg. 49008 (Sept. 21, 1993).

o Safe harbor protection for malpractice subsidies for obstetrical care in Health care manpower shortage areas. 58 Fed. Reg. 49008 (Sept. 21, 1993).

o Safe harbor protection for referral arrangements in which referrals are made for specialty services not within the medical expertise of the referring individual or entity in return for an agreement to refer the patient back. 58 Fed. Reg. 49008 (Sept. 21, 1993).

o Payments from a patron-hospital to a cooperative hospital service organizations ("CHSOs") that are tax exempt under Section 501(c)(3) of the Internal Revenue Code would be protected under the proposed safe harbor. 58 Fed. Reg. 49008 (Sept. 21, 1993).

E. Potential areas of concern for consultant pharmacists

o Pharmacy pays long-term care facility to handle pharmacy's billings to inpatients. Kickback risks significant if payment exceeds fair market value of billing. Cf. Sullivan's Wholesale Drug Co. v. Faryl's Pharmacy, 214 Ill. App. 3d 1073, 573 N.E.2d 1370 (1991) (consumers deceived where nursing home did not disclose to residents that it received 15% fee from pharmacy for billing services; pharmacy servicing residents liable under Illinois consumer fraud act to former pharmacy that had refused to enter into alleged "kickback" arrangement).

o Pharmacy provides carts or other equipment at no charge for use at a long-term care facility in delivering or administering prescription drugs to inpatients. If activity is merely part of the quality service the pharmacy provides to fulfill its responsibility to patients, fraud and abuse problem not likely. Questions more serious if pharmacy's offer includes services that would normally be the responsibility of the facility itself.

o Company buys nursing home chain's pharmacy subsidiary and sets purchase price on basis of future sales of drugs to inpatients of facilities. Risk that portion of purchase price is inducement to refer Medicaid or Medicare business. Issue could also arise if company buys nursing home's in-house pharmacy for amount that exceeds tangible net worth, and includes value as ongoing concern or goodwill. To the extent purchase price appears to include compensation for value of future services by pharmacy to facility's residents, fraud and abuse issues could arise.

o Consultant pharmacy rents space within facility for performance of consulting services. Parties could try to fit arrangement within lease safe harbor. But, if no rent would be charged at all in a fair market transaction, if the space is not actually needed by the pharmacist, or if "full-time" rent is paid for space that is only occasionally used, the rental payment would not qualify for safe harbor protection. Similar questions if consulting pharmacy rents storage space for supplies it sells to the facility directly or that are held for eventual purchase by patients.

> Note: Under Medicare Provider Reimbursement Manual, rental payments from a supplier for storage of supplies in a hospital or extended care facility that are sold to facility itself is considered a discount on the price of the supplies purchased by facility from supplier. Such a discount must be reflected in the facility's cost report to the Medicare program.

o Pharmacy provides free car to long-term care facility to use in picking up and dropping off prescription medications prepared by the pharmacy. Deal could be suspect as in-kind remuneration to induce referrals to the pharmacy.

* o Provision of consulting services to long-term care facility at no or at reduced charge in consideration for status as preferred dispensing pharmacy to inpatients of facility. Although enforcement officials have not yet spoken on this topic, pharmacies and facilities would have greatly increased protection from fraud and abuse allegations if fair market rate were paid for consulting and staff training services, and availability of consulting services were not tied to status as provider of pharmaceuticals to inpatients.

o Consulting pharmacy pays long-term care facility to fill out forms needed for pharmacy to bill and collect reimbursement from state Medicaid program. Personal services safe harbor likely not available. If payments exceed true fair market value, risk may be significant.

o Medicare generally reimburses up to two catheters per month of parenteral nutrition. The long-term care facility may sometimes use three, either because one of the two was defective, or simply because in its judgment, more than two are medically necessary. Pharmacy waives charge for third. Risk seems limited.

o Pharmacy gives facility unrelated goods, such as oxygen concentrator, in exchange for opportunity to sell covered items to facility or its inpatients. Significant risk exposure possible.

o Manufacturer gives volume rebate to pharmacy, that buys from wholesaler. Not likely enforcement action, even if transaction not structured to fit within safe harbor for discounts. Risk may be increased if pharmacy also provides consulting pharmacist services and is thereby in position to induce increased or continued use of drug by facility residents. Individual consulting pharmacist might be kept out of "rebate" loop, but this may run counter to trend toward "managed care" concepts in drug management.

o Long term care pharmacy "sells" items at a discount to middle-man entity that "sells" Medicare-covered items to long term care facility residents. Pharmacy handles direct delivery to patients. Arrangement could be structured to fall within "discount" safe harbor, if arrangement has indicia of bona fide sale. To qualify fully for safe harbor, reporting of discount would be required. Arrangement could also be designed to permit billing of DME items through different Medicare carrier from other state. Federal government is moving toward system that will prevent "carrier-shopping" by DME providers.

II. PHYSICIAN SELF-REFERRAL PROHIBITIONS

Also of possible interest to consultant pharmacists is the extension of 42 U.S.C. section 1395nn to outpatient prescription drugs. This law would ban physician referrals to a pharmacy in which the physician has a financial interest.

Under the amended version of section 1395nn, a physician may not refer a patient to certain entities with which the physician has a "financial relationship", if payment for services of the entity rendered to the referred patient may be made under the Medicare or Medicaid programs. The entity is also prohibited from presenting a claim for payment under the Medicare or Medicaid programs if the patient for whom the claim is made has been referred by a physician with a financial relationship with the entity.

o A "financial relationship" under the amendments is defined to include an ownership or investment interest in the

entity, whether through equity or debt, and a compensation arrangement between the physician and the entity.

- A compensation arrangement is further defined to mean any remuneration between an entity and the physician, including debt forgiveness, and provision of services at below fair market value, with narrow exceptions.

- Investment interests include those that a referring physician owns indirectly through a holding company.

- Certain exceptions are available for both compensation and investment interests.

- Medicare or Medicaid payments will not be made for ancillary health services provided in violation of the ban.

- Penalties also include civil fines of up to $15,000 per improper referral. There is also authority for exclusion of a provider from the Medicare or Medicaid program for knowing violations of the self-referral prohibitions.

III. OTHER FRAUD AND ABUSE PRACTICES

A. Altering physician prescriptions.

B. Improper filling of prescriptions with samples.

C. Improper labeling and refilling.

D. Improper repackaging of pharmaceuticals.

E. Submitting claim for brand name drug, when generic was dispensed.

F. Over-aggressive telemarketing for DME.

G. "Shopping" for Medicare carrier with favorable reimbursement approach.

H. Improper waiving of copayments

I. Distributing completed or partially completed certificates of medical necessity to physicians; misleading physicians into signing certificates.

J. Billing for components of item that can be singly billed.

K. Billing for extended lease period, when sale would be cheaper.

L. False computer-generated tape-to-tape billing of prescriptions.

M. Facilities billing Medicare for "take home" drugs, since Medicare does not cover outpatient drugs.

N. Selling or renting used DME as new.

IV. POSSIBLE DIRECTIONS

A. Enforcement trend.

o Direction is toward increased enforcement, targeting illegal remuneration and other practices that increase utilization and per unit costs, or compromise quality. Law enforcement agencies are using medical record review, making field purchases to compare Medicaid and "retail" prices, reviewing bills, and doing undercover operations. Scores of FBI agents transferred from national security to health care fraud and abuse.

o Safe harbors and recent prosecutions are leading many firms in consulting pharmacy, home health care, IV therapy, and similar fields to restructure previous deals to avoid or lessen fraud and abuse risk.

o Fraud and abuse enforcers have not focused heavily, to date, on relationships among dispensing pharmacy/long term care facility/consulting pharmacist, perhaps because it may be hard to identify harm to public in some instances. Medicaid prescription costs are regulated, and increasing costs to nursing home would not tend to get passed on to government. This lack of enforcement may change. Consulting pharmacist may be in position to influence frequency and choice of prescription drugs.

o Significant risk evolving of private legal action from disgruntled competitor who loses business due to alleged improper arrangement between consulting pharmacy and long term care facility.

o State anti-kickback laws also exist in nearly every state with respect to the Medicaid program. These laws are largely mirrored on the federal fraud and abuse statute. In addition, more states are beginning to enact anti-kickback laws with respect to non-governmental payers, also usually modeled on the federal law. These states include Texas, South Carolina and Virginia. Although we are not aware of any enforcement activity to date, states may become increasingly concerned about relationships between pharmacies and nursing homes because of the state's expenditure of substantial funds on both nursing home and prescription drugs under the Medicaid program.

B. Customer needs trend.

o Some facilities now more gun-shy about "deals". Specific proposals sought that are crafted to avoid fraud and abuse exposure.

o Long-term care facility pharmacies under increased pressure from FDA not to "repackage" drugs and to avoid large-scale "compounding" operations.

o State and federal requirements are making documentation and billing for services to facility inpatients more complicated and burdensome.

o Facilities may look for pharmacies that can reduce administrative hassles and time commitments.

o Evolving technology may foster expectation for enhanced capacity to provide quality service on a centralized basis.

STATE OF MAINE

DEPARTMENT OF HUMAN SERVICES

PRINCIPLES OF REIMBURSEMENT

FOR

LONG-TERM CARE FACILITIES

A REIMBURSEMENT SYSTEM FOR

MEDICAID PATIENTS IN A

NURSING FACILITIES

IN THE STATE OF MAINE

EFFECTIVE OCTOBER 1, 1990, AND THEREAFTER

expenses, or mortgage fees in the event of new construction, are to be amortized over a 60 month period.

4170 **Costs Attributable to Asset Sales.** Costs attributable to the negotiation or settlement of a sale ~~of~~ or purchase of any capital asset (by acquisition or merger) are not allowable costs. Included among such unallowable costs are: legal fees, accounting and administrative costs, appraisal fees, banking and broker fees, travel costs and the costs of feasibility studies.

5000 SPECIAL SERVICE ALLOWANCE

5010 **Principle.** A special service is to be distinguished from a routine service. Special services are of two types:

5010.1 One type of special service is that of an individual nature required in the case of a specific patient. This type of service is limited to professional services such as physical therapy, occupational therapy, and speech and hearing services. Special services of this nature must be billed monthly to the Department as separate items required for the case of individual recipients.

5010.2 Another type of special service is that rendered for the benefit of a group of patients in the facility rather than an individual recipient.

These types of consultative services will be considered as part of the allowable per diem cost:

* Pharmacist Consultants
* Dietary Consultants
* Medical Directors
* Social Worker Consultants
* Advisory Dentists

(See Sections 5011-5017)

5011 **Pharmacist Consultants.** Pharmacist consultants will be paid directly by the facility, which will then be reimbursed through the per diem rate. In addition to any pharmacist consultant fees included in the base year rate, up to $2.50 per month per resident shall be allowed for drug regimen review.

5012 **Dietary Consultants.** Dietary Consultants professionally qualified, may be employed by the facility or by the Department. If employed by the

ANDREW KETTERER
ATTORNEY GENERAL

Telephone: (207) 626-8800
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STATE OF MAINE
DEPARTMENT OF THE ATTORNEY GENERAL
6 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0006

REGIONAL OFFICES:

84 HARLOW ST., 2ND FLOOR
BANGOR, MAINE 04401
TEL: (207) 941-3070
FAX: (207) 941-3075

59 PREBLE STREET
PORTLAND, MAINE 04101-3014
TEL: (207) 822-0260
FAX: (207) 822-0259

March 13, 1996

Ronald J. LaVallee, R.Ph.
Downeast Pharmacy, Inc.
P. O. Box 2546
Bangor, Maine 04401

Dear Mr. LaVallee:

Thank you for your letter of February 9, 1996, calling to our attention a situation which you described as an appearance of unprofessional conduct as well as possible violations of law by , R.Ph., of Pharmacy. While there is an anti-kickback statute at the federal level, which may have application here, we have no such companion statute at the state level. Accordingly, we have referred this information to the United States Attorney's Office.

If you have any questions or want to discuss any of this matter further, feel free to contact us.

Sincerely,

BRIAN MacMASTER
Director of Investigations
Department of the Attorney General
Tel: (207) 626-8520

Appendix #1

Effective 10-16-94

Supplies and Equipment provided to recipient by a NF as part of regular rate of reimbursement.

The following items may not be billed by either the facility or supplier. Facilities which service a special group of the disabled are expected to furnish that equipment which is normally used in their care (e.g. children's wheelchairs) as a part of their reasonable cost.

Routine supplies and personal care items which are provided by the NF under 67.05-11(A), may not be purchased by a resident and then deducted from their cost of care. The NF must provide any brand name item to the resident as part of the NF regular rate of reimbursement if the resident has a therapeutic need as documented by the physician.

1. Alcohol, swabs and rubbing
2. Analgesics: (non-prescription): 1) Acetaminophen: tablets, 325 mg, 500 mg; liquid; suppositories, 325 mg, 650 mg. 2) Aspirin: tablets, 325 mg, plain, buffered, coated; suppositories, 325 mg, 650 mg.
3. Antacids: aluminum/magnesium hydroxide: gel and tablets (ex. Maalox). 2) Aluminum/magnesium hydroxide with simethicone (ex. Mylanta, Maalox Plus). 3) Calcium carbonate tablets (ex. Tums). 4) Calcium carbonate/magnesium hydroxide tablets (ex. Rolaids).
4. Alternating pressure pads, air mattresses, "Egg Crate" mattresses, gel mattresses
5. Applicators
6. Bandages
7. Bandaids
8. Basins
9. Beds (standard hospital type, not therapy beds)
10. Bed pans
11. Bed rails
12. Blood pressure equipment
13. Bottles (water)
14. Canes
15. Calcium supplements: 1) Calcium carbonate (ex. Tums). 2) Calcium carbonate with vitamin D (ex. Oscal)
16. Catheters
17. Catheter trays (disposable)
18. Chairs (standard, geriatric)
19. Combs
20. Commodes
21. Corner chair
22. Cotton
23. Syrups/expectorants (non-prescription) 1) Guiafensin (ex. Robitussin). 2) Guiafensin - DM (ex. Robitussin DM) 3) Ammonium chloride/diphenhydramine (ex. Benylin).
24. Crutches
25. Cushions (e.g., comfort rings)
26. Dietary supplements
27. Disinfectants
28. Douche trays (disposable)
29. Dressings

Appendix #1 (Cont.)

30. Enema equipment
31. Enteral feedings, supplies and equipment
32. Facility deodorants
33. Gauze bandages (sterile or unsterile)
34. Glucometers
35. General services such as administration of oxygen and related medications, hand feeding, incontinency care, tray service, and enemas
36. Gloves (sterile)
37. Gloves (unsterile)
38. Gowns
39. Hemorrhoidal preparations
40. Ice bags
41. Incontinent supplies: full brief - all sizes; bed pads; undergarment liners, disposable or reusable; under pads.
42. Irrigation trays
43. Laundry services, personal (including supplies and equipment)
44. Laxatives: Stool softeners: docusate sodium liquid or capsule. Bulk: psyllium. Stimulants: Bisacodyl tablets and suppositories; docusate casanthranol, liquid and/or capsule. Enemas: saline; phosphate types (ex. Fleets); oit retention. Misc.: Milk of Magnesia; glycerin suppositories; lactulose and analogs (when used as a laxative); mineral oil.
45. Lotions (emoliant)
46. Lubricants (skin, bath oil)
47. Mouth wash
48. Ointments and creams (available over the counter), including petroleum jelly, and hydrocortisone 0.5%
49. Ophthalmic lubricants: tears, ointments
50. Oxygen, for emergency and prn use only
51. Parenteral solutions, supplies and equipment
52. Pillows
53. Pitchers (water)
54. Powders (medicated and baby)
55. Prone boards
56. Rectal medicated wipes
57. Restraints (posey, thoracic chest supports, tilt in space chairs, wedge pillows, etc.)
58. Shampoo: three types: 1) regular; 2) medicated; and 3) no tears - baby shampoo
59. Sheepskin
60. Shower chairs
61. Soap: include one hypoallergenic type
62. Special dietary supplements
63. Specimen containers
64. Sterile I.V. or irrigation solution
65. Stethoscope
66. Sunscreen - level 30
67. Supplies (non-prescription)necessary for the treatment of decubiti
68. Suture sets
69. Swabs, medicated or unmedicated
70. Syringes and needles
71. Tapes
72. Testing materials to be used by staff of facility
73. Thermometers

Appendix #1 (Cont.)

74. Tissues
75. Toothbrush
76. Toothpaste - two types accepted by ADA; and a denture cleanser
77. Towels, washcloths
78. Tongue depressors
79. Traction equipment
80. Trapezes
81. Tub seats
82. Tubes (gavage, lavage, etc.)
83. Urinals
84. Urinary drainage equipment and supplies (disposable)
85. Vitamins: two brands acceptable to pharmacy and dietary
86. Walkers
87. Wheelchairs - standard, including those with removable arms and leg rests, pediatric, "hemi" chairs, reclining wheelchairs
88. Routine personal hygiene and grooming to include, but not be limited to: shave, shampoo, bathing, nail clipping (unless specified as a covered service by a podiatrist in the Maine Medical Assistance Manual), unless the services of a barber or hairdresser are requested by and paid for by the resident
89. Routine transportation of residents or laboratory specimens to hospital or doctors' offices

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PRESCRIPTION DRUG USE IN NURSING HOMES

Report 1

An Introduction Based on Texas

JUNE GIBBS BROWN
Inspector General

November 1997
OEI-06-96-00080

EXECUTIVE SUMMARY

PURPOSE

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

BACKGROUND

Payments for prescription drugs represent a large portion of Medicaid's expenditures for nursing homes. In fiscal year 1995, Medicaid payments for prescription drugs reached $9.8 billion. Medicaid provided services for 1.7 million nursing home residents in the same year. Prescription drug costs are estimated to range from $600 to $1000 per resident. This implies that between $1 billion and $1.7 billion of those payments went for prescription drugs in nursing facilities.

Several recent studies suggest that the use of inappropriate or contraindicated drugs is a contributing factor to the high health care costs in the elderly population. The primary goal of drug therapy for nursing home patients is to maintain and improve, to the extent possible, the patient's functional capacity and quality of life. The Omnibus Budget Reconciliation Acts (OBRA) of 1987 and 1990, in recognition of this, require the regulation of certain drugs in nursing homes and the establishment of drug utilization review programs for nursing home residents. Provisions of the OBRA 1990, while not required for all nursing homes, also clearly establish Congress' desire to involve pharmacists more actively in patient care.

We undertook this inspection, using three different approaches, to provide insight into several issues related to prescription drug use in nursing homes. These issues are addressed in three reports, of which this is the first. To assess the extent of prescription drug use for Medicare and Medicaid nursing home residents, we obtained Medicaid data for Texas for calendar years 1992 through 1994 and the first six months of 1995.[1] We report total program expenditures by year and total expenditures by drug class, offering a more detailed understanding of precisely what types of drugs are being used in nursing homes and in what volume they are being used. We also consider expenditures on drugs regulated by the OBRA 1987 or deemed inappropriate for use in elderly populations.

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

FINDINGS

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

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

- The average payment per beneficiary increased 20 percent from 1992 to 1994, much faster than the one percent increase in beneficiaries receiving drugs and substantially greater than the rate of inflation for this period.

- Drug payments for this population are a significant portion of State and Federal program expenditures; more than 17 percent ($91 million) of Texas' total prescription drug payments of $535 million were for the Medicare and Medicaid nursing home population.

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

It is important to understand that reports of possible "inappropriate" use of medications are somewhat a matter of opinion. Ultimately, for nursing home patients, it is either the patient's attending physician or the facility's medical director who determines what is appropriate care.

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

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

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

- Gastrointestinal drugs, drugs for cardiovascular and cardiac care, psychotherapeutics, and antiinfective drugs combine to total more than half of Medicaid payments for prescription drugs in this population.

- Total payments for drugs in these categories increased at very high rates, ranging from 60 percent to 94 percent, between 1992 and 1994.

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

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

- Almost 47 percent of the residents in our dataset received at least one gastrointestinal drug in 1994; their total cost to Medicaid was over $15 million. This single drug class accounted for almost 17 percent of all Medicaid prescription drug payments in that year, a substantial increase over the 1992 share of 12 percent.

- This class of drugs is one of the most expensive, with average payments per beneficiary of nearly $385 and an average cost per day of $1.05.

- A 1992 study suggests that at least 40 percent of nursing home residents who receive these drugs are receiving them for conditions other than those indicated in the medical literature. Therefore, curtailing unnecessary or inappropriate use of gastrointestinal drugs could result in sizeable program savings.

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

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

RECOMMENDATIONS

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

COMMENTS ON THE DRAFT REPORT

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

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).

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).

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PRESCRIPTION DRUG USE IN NURSING HOMES

Report 3

A Pharmaceutical Review
and
Inspection Recommendations

JUNE GIBBS BROWN
Inspector General

NOVEMBER 1997
OEI-06-96-00082

EXECUTIVE SUMMARY

PURPOSE

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

BACKGROUND

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

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

FINDINGS

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

Quality of Care Issues

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

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

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

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

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

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

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

Shortcomings of Medication Reviews

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

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

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

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

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

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

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

RECOMMENDATIONS

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

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

COMMENTS ON THE DRAFT REPORT

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

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

Departmental Comments

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

Comments from External Organizations

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

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

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

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

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

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

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

A Clinical & Cost Reference Tool
For Use in Geriatric, Long-Term Care

GERIATRIC PHARMACEUTICAL CARE GUIDELINES

1997/98 EDITION

Clinical Evaluations:

Philadelphia College of
Pharmacy and Science

The Omnicare Formulary

Geriatric Pharmaceutical Care Guidelines Clinical Rating System

PREFERRED

- Overwhelming evidence of distinguishing positive effects or outcomes compared with other agents in the class when used in a nursing facility resident population.
- Literature documented superior effects, less potential for or prevalence of adverse reaction(s), or some unique characteristic that provided a clear advantage over other agents in the class when used in a nursing facility resident population.

ACCEPTABLE

- Comparable efficacy and safety with minimal distinguishing characteristics (e.g., therapeutic outcome, functional improvement) when used in a nursing facility resident population.

UNACCEPTABLE

- Literature documented increased prevalence or severity of adverse reaction(s) *and* equally effective, safer alternatives existing within the same therapeutic class when used in a nursing facility resident population.
- Lack of documented therapeutic efficacy in a nursing facility resident population.

Indication:

Angina Pectoris, Chronic, Stable

Drug Class:

Calcium Channel Blockers

Clinical Rating:*

Generic (Brand)	Geriatric Dosage Range**	Relative Cost
Preferred:		
Dihydropyridines		
Amlodipine (NORVASC®)	2.5 - 10 mg/day	$$
Nicardipine	60 - 120 mg/day	$$
Nifedipine SR (PROCARDIA® XL)	30 - 120 mg/day	$$$
Benzothiazepine Derivatives		
Diltiazem SR (CARDIZEM® CD)	120 - 360 mg/day	$$$
Diltiazem SR (DILACOR® XR)	120 - 360 mg/day	$$$$
Acceptable:		
Dihydropyridines		
Nifedipine (ADALAT®)	30 - 180 mg/day	$$$
Diphenylalkylamine Derivatives		
Verapamil	120 - 480 mg/day	$
Verapamil SR	120 - 480 mg/day	$
Verapamil SR (COVERA® HS)	120 - 480 mg/day at bedtime	$$
Benzothiazepine Derivatives		
Diltiazem (CARDIZEM®)	90 - 360 mg/day	$$$
Unacceptable:		
Diarylaminopropylamine Derivative		
Bepridil (VASCOR®)		

**Preferred:* Documented distinguishing positive effect or outcomes vs. other agents in nursing facility resident populations or lesser potential/prevalence of adverse drug reactions, or some unique characteristic, which provides a clinical advantage.

Acceptable: Comparable efficacy and safety with minimal distinguishing characteristics in nursing facility resident populations.

Unacceptable: Greater prevalence or severity of adverse reactions or lack of documented therapeutic efficacy vs. other agents in nursing facility resident populations.

**See references for geriatric dosage ranges on page 12.

Summary of Findings:

Pharmacology

The calcium channel blockers are a heterogenous group of agents in their chemical structure and global effects on the cardiovascular system.[1] They are all effective in inhibiting slow-channel transport across the cell membrane. However, their action on the cardiovascular system seems to fall into two distinct groups. Verapamil and diltiazem have nonspecific action on the sympathetic nervous system, and they block atrioventricular conduction, producing a mild bradycardia at rest. The dihydropyridines have no action on the atrioventricular conduction and enhance the sympathetic activity by their potent peripheral vasodilatation action, which explains the reflex tachycardia seen with these agents.[1]

Since the heart rate is a major determinant of myocardial oxygen consumption, the agents that have an inherent capacity to reduce resting heart rate may possess myocardial oxygen demand-sparing properties,[2] and thus, in theory, may be more efficacious as monotherapy in patients with chronic, stable angina.[1] In addition, there is no evidence that the negative inotropic effect associated with verapamil is more prominent in the elderly, but that serious adverse negative effects on cardiac conduction are less likely.[3,4]

Bepridil also has sodium channel blocker properties and prolongs the effective refractory periods of the atria, atrioventricular node, His-Purkinje system and the ventricles.[5] Bepridil exerts its antianginal effect by reducing myocardial oxygen consumption and improving coronary blood flow with little reduction in systemic blood pressure and lesser negative inotropic potential than other calcium antagonists. Bepridil also favorably alters the distribution of coronary blood flow during exercise in patients with coronary artery disease.[6]

Pharmacokinetics

All calcium channel blockers are extensively metabolized by the liver, and dosage adjustment may be necessary in patients with impaired hepatic function.[7]

Efficacy

Verapamil,[8] diltiazem,[9] felodipine,[10] nifedipine,[11] nicardipine,[12] amlodipine[13-15] and bepridil[5] have been shown to be effective in the treatment of chronic, stable angina. Comparative trials evaluating the efficacy of calcium channel blockers in the treatment of chronic, stable angina showed that all agents are effective in increasing exercise tolerance and in decreasing angina episodes and sublingual nitroglycerin consumption.[5,16-24] Bepridil has also been shown to be effective in patients refractory to, or intolerant of, other antianginal treatments.[5]

Literature evaluation of the use of calcium channel blockers in the treatment of angina pectoris suggests that verapamil, diltiazem, nifedipine, nicardipine and amlodipine have equal efficacy and safety profiles, with the exception of a greater incidence of verapamil-induced constipation when used in elderly patients, and are thus, Preferred agents for this indication. The increased

risk of potential cardiac arrhythmias associated with the use of bepridil renders this agent Unacceptable. However, bepridil can be a useful antianginal agent in patients who are intolerant of, or who are refractory to, conventional antianginal regimens.

Safety and Toxicity

The safety of calcium channel blockers in the treatment of angina has been confirmed in clinical trials.[5,9-24] However, recent meta-analyses and observational studies[25-27] conclude that patients receiving a short-acting calcium channel blocker have a greater risk of myocardial infarction. The calcium channel blockers used included short-acting nifedipine and diltiazem preparations for the treatment of hypertension. It is believed that such short-acting calcium channel blockers can induce recurring sympathetic neurohormonal activation and evoke a reactive cardioacceleration, which may be detrimental in patients with underlying myocardial disease. Until these findings can be validated in prospective studies, short-acting calcium channel blockers should be considered Acceptable agents for the treatment of chronic, stable angina rather than Preferred agents.

Even though an acceptable safety profile has been established for bepridil, its electrophysiologic effect has raised concern about its proarrhythmogenic potential, and bepridil should be reserved for patients with chronic, exertional angina who are refractory to, or intolerant of, conventional therapy.[28]

Quality of Life

There are no published studies evaluating the effect of calcium channel blockers on the quality of life in nursing facility residents with angina pectoris.

Nursing Facility Resident Considerations

Due to the co-morbidity in elderly residents with coronary artery disease and the differing effects of calcium channel blockers upon the cardiovascular system, the choice of a calcium channel blocker for the treatment of angina pectoris must be individualized.

Drug Administration Considerations

Verapamil is associated with the most drug-drug interactions. All calcium channel blockers have comparable monitoring requirements. The timing and frequency of calcium channel blocker therapy for angina pectoris are dependent upon the resident's symptoms. Of the Preferred agents, amlodipine and the extended-release formulations of diltiazem and nifedipine can be administered once daily. Nifedipine capsules can be punctured and given via feeding tubes.

Preferred Agents: Amlodipine, Diltiazem SR, Nicardipine and Nifedipine SR

Literature evaluation of the use of calcium channel blockers in the treatment of angina pectoris suggests that amlodipine, nicardipine and long-acting nifedipine and diltiazem preparations have equal efficacy and safety profiles for use in elderly patients, and are thus, Preferred agents for this indication. The safety profile of short-acting calcium channel

blockers remains controversial for patients with underlying myocardial disease. Until large prospective studies are conducted to validate their safety, short-acting calcium channel blockers should be considered Acceptable agents. In addition, verapamil is not a Preferred agent because of its frequency in causing constipation in elderly patients and interacting with other drugs.

Unacceptable Agent: Bepridil

The increased risk of potential cardiac arrhythmias associated with the use of bepridil renders this agent Unacceptable. However, bepridil can be a useful antianginal agent in patients who are intolerant of, or refractory to, conventional antianginal regimens.

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