

# TABLE OF CONTENTS

	page
Executive Summary	
Introduction .....	1
Reimbursement Formulas .....	2
Consulting Pharmacists, Fees, Potential Conflicts .....	4
Rules on Dispensing of Medication .....	8
Vertical Integration and Conflict of Interest .....	9
The Practice of Over-Prescribing .....	10
Stocking Patterns for Standard, Nonchargeable Medical Supplies .....	11

## APPENDICES

- 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

H. Letter from Department of the Attorney General Regarding Lack of State Anti-kickback Law

I. Excerpt from the Maine Medical Assistance Manual Regarding Routine Supplies

J. Executive Summaries of Three Reports by the Office of Inspector General on Prescription Drug Use in Nursing Homes, November 1997

- Report 1: An Introduction Based on Texas
- Report 2: An Inside View by Consultant Pharmacists
- Report 3: A Pharmaceutical Review and Inspection Recommendations

K. Example of Geriatric Pharmaceutical Care Guidelines

## 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 by 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 increased 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 manage 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.

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