

CENTER FOR HEALTH POLICY RESEARCH

COLLEGE OF OSTEOPATHIC MEDICINE
2345 SOUTHWEST BOULEVARD, TULSA, OK 74107

The logo for Oklahoma State University (OSU) is displayed in white text on an orange square background. The letters 'O', 'S', and 'U' are large and stylized, with a small triangle inside the 'O'.

AN ISSUE PAPER RESOURCE SUPPLEMENT



• PRESCRIPTION MEDICINES & NURSING HOMES • **LAWS - LETTERS - REPORTS - POLICIES**



Introduction

This document supplements our Health Policy Brief: Prescription Medicines & Nursing Homes, A Problem - A Solution. It provides full, unedited text, of all major source documents. Underlining has been added for emphasis.

Exhibit 1

Oklahoma Statute 59-353-24

Originally enacted in 1961; amended several times.

Unlawful acts:

It shall be unlawful for any person, firm, or corporation to:

Forge or increase the quantity of drug in any prescription or to present a prescription bearing forged, fictitious, or altered information or to possess any drug secured by such forged, fictitious, or altered prescription;

Sell, offer for sale, barter, or give away any unused quantity of drugs obtained by prescription ... (added in 1993: "except as provided by the State Board of Pharmacy");

Sell, offer for sale, barter, or give away any drugs damaged by fire, water, or other causes without first obtaining the written approval of the Board or the State Department of Health;

Enter into any arrangement whereby prescription orders are received or prescriptions delivered at a place other than the pharmacy in which they are compounded and dispensed;

However, nothing in this paragraph shall prevent a pharmacist or his employee from personally receiving a prescription or delivering a legally filled prescription at a residence, office, or place of employment of the patient for whom the prescription was written;

Sell, offer for sale, barter, or buy any professional samples. For the purpose of this paragraph, "professional samples" means complimentary drugs packaged in accordance with federal and state statutes and regulations and provided to a licensed practitioner free of charge by manufacturers or distributors for the purpose of being distributed free of charge in such package by the licensed practitioner to his patient;

Refuse to permit or otherwise prevent members of the Board or such representatives thereof from entering and inspecting any and all places including premises, equipment, contents, and records where drugs, medicine, chemicals, or poisons are stored, sold, vended, given away, compounded, dispensed, or manufactured.

Exhibit 2

FDA Compliance Policy Guide 460.300

October 1, 1980

Return of Unused Prescription Drugs
to Pharmacy Stock

A pharmacist should not return drug products to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons because he would no longer have any assurance of the strength, quality, purity, or identity of the articles.

Many state boards of pharmacy have issued regulations specifically forbidding the practice. We endorse the actions of these state boards as being in the interest of public health.

The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise should he mix returned portions of drugs to his shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.

Exhibit 3

AMA Policy Statement Issued 2/1/97 Recycling of Nursing Home Drugs

Consistent with the policy of the American Society of Consultant Pharmacists (ASCP), the AMA supports the return and reuse of medications to the dispensing pharmacy to reduce waste associated with unused medications in long-term care facilities and to offer substantial savings to the health care system provided the following conditions are satisfied: 1) the returned medications are not controlled substances, 2) the medications are dispensed in tamper-evident packaging and returned with packaging intact (e.g., unit dose, unused injectable vials and ampules), 3) in the professional judgement of the pharmacist, the medications meet all federal and state standards for product integrity, 4) policies and procedures are followed for the appropriate storage and handling of medications at the LTCF and for the transfer, receipt, and security of medications returned to the dispensing pharmacy, 5) a system is in place to track re-stocking and reuse to allow medications to be recalled if required, 6) a mechanism (reasonable for both the payer and dispensing pharmacy) is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source.

Exhibit 4

Oklahoma Board of Pharmacy Response to TCMS

Letter to Dr. William Geffen, President, Tulsa County Medical Society
from Bryan Potter, Executive Director, Oklahoma Board of Pharmacy
September 24, 1998

Your letter was reviewed during the September Board meeting. The Board is unable to modify the regulations to accomplish your suggestions at this time. Let me explain the multiple factors in allowing the return of these prescription medications.

- This is unlawful by statute - Title 59, Chapter 8, Title 535, Section 353.24 (this would require legislative change).
- To change this law would place the State law in direct conflict with the Food and Drug Administration (FDA) Compliance Policy Guidelines Chapter 4, Section 460.300. The pharmacist or doctor is legally responsible for all hazards of contamination or adulteration that may arise from returned portions of drugs. The manufacturer can not be held liable for medications returned to stock.
- The federal law under DEA does not allow the transfer of CDS to anyone other than the patient for which the medication is prescribed.
- The State Health Department Rules on Nursing Homes require that all expired and unused medication be destroyed by the Director of Nursing and the consultant pharmacist.

- The blister pack medications are heat sealed and the UPS standard for expiration date for these medications are 6 months or 1/4 of the date listed on the original container. To remove the drugs from a bubble pack would require a maximum expiration of 45 days.

Hospitals are allowed to return drugs to the pharmacy. They issue single dose units and the medications are never out of the institution. We anticipate that in the very near future, nursing homes will be dispensing only small quantities of medications with very little medication left to destroy.

I am sure you are aware of the programs available by a number of manufacturers that furnish drugs for the indigent patients at no cost. The charitable clinics are allowed to use samples for these indigent patients

We appreciate your concerns, however we are unable to correct or change the law at this time.

Exhibit 5

FDA Response to AMA

Letter to E. Ratcliffe Anderson, Jr., M.D. Executive Vice President, CEO, AMA
from Janet Woodcock, M.D., Director FDA Center for Drug Evaluation and Research
February 25, 2000

Your letter of November 3, 1999, requesting clarification of FDA policy on the return of unused, sealed, and dated drugs from nursing homes or long-term care facilities was referred to this office for response. Specifically, you asked about the agency's Compliance Policy Guide 460.300 concerning the return of unused, dispensed medications to a pharmacy.

The agency recognizes that the current medical care environment requires optimizing both patient care and cost management. One means for containing costs is the recovery of medications dispensed but unused in institutional medical care/treatment settings, such as you described.

Your letter expresses the concern that CPG 460.300 may present an obstacle to recovery of these medications. However, CPG 460.300, which was issued in 1980, seems to be particularly directed towards returns to stock of unused portions of prescription drugs dispensed to patients (e.g., drugs that are dispensed to patients in pharmacy bottles from the manufacturer's packaging). Because the conditions outlined in your letter include the requirement that the medications be dispensed in unbroken, tamper-evident packaging and returned with the packaging intact, it would seem that this would protect against at least some of the concerns the CPG was designed to address.

Therefore, the agency [FDA] would not object if sealed, tamper-evident, within-date medications are returned to the dispensing pharmacy by nursing homes or other LTCFs if the AMA requirements are met and:

- The dispensing pharmacy is affiliated with the nursing home or LTCF as evidenced by a written business or contractual agreement or other written documentation that the pharmacy is operating as the pharmacy for the health care entity
- The pharmacy and responsible pharmacist(s) are licensed and in good standing under applicable state law
- The dispensed medications have not left the control of the nursing home or LTCF after they were received from the pharmacy
- The storage, handling, and record keeping systems of the nursing home or LTCF are adequate to document how the returned medications have been handled while out of the control of the dispensing pharmacy. Special attention must be given to documenting the storage conditions maintained for medications that require special storage conditions (e.g., refrigeration)
- Only medication that has been dispensed in the original manufacturer's packaging may be returned

FDA's Good Guidance Practices (February 27, 1997) state that official statements of agency policy are to be expressed in guidance documents that are developed in a public process. Therefore, this letter should be considered an informal opinion of the agency and does not constitute an official statement of agency policy.

Exhibit 6

Engrossed House Bill 2593

Oklahoma House of Representatives - No action taken, March 30, 2000

An act relating to public health and safety; requiring the State Board of Health and the Board of Pharmacy to develop a program to redistribute unused prescription drugs; providing exception; requiring promulgation of rules; and providing an effective date.

Be it Enacted by the People of the State of Oklahoma:
Section 1: A new section of law to be codified in the Oklahoma Statutes as Section 2-522 of Title 63, unless there is created a duplication in numbering, reads as follows:

A: The State Board of Health and the Board of Pharmacy shall jointly develop a program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled dangerous substances by Section 2-101 of Title 63 of the Oklahoma Statutes, may be transferred from nursing homes to repositories established for the purpose of distributing the medication to Oklahoma residents who are medically indigent.

B: The State Board of Health and the Board of Pharmacy shall promulgate rules and establish procedures necessary and appropriate to implement ...

Exhibit 7

Request for Interim Study Committee

Letter to Senator Stratton Taylor, Senate President Pro Tem
from Senator Bernest Cain, May 24, 2000

... I would like to respectfully request a Joint House-Senate Interim Study Task Force on the Utilization of Unused Prescription Medications of this Interim. I would request that the following people be appointed to this Interim Study: ...

Exhibit 8

Oklahoma Senate Interim Study Committee

Utilization of Unused Prescription Medications (Joint)

Requested by: Senator Bernest Cain
Assigned to: Special Joint Interim Committee
Chair: Senator Bernest Cain
Other Members: Senator Ben Robinson, Mr. John Donner, Mr. Michael Fogarty, Mr. Bryan Foy, Mr. Howard Hendrick, Ms. Lynette McLain, Mr. Bryan Potter, Mr. Jerry Regier

Senate Staff:
Connie Johnson, Legislative Analyst
Brenda Price, Attorney
David Blatt, Fiscal Analyst
Sara Lassiter, Administrative Assistant

The House component of this joint effort is not yet finalized. Rep. Darrell Gilbert has requested an interim study committee. Any House effort would likely originate in the House Public Health Committee chaired by Rep. Fred Stanley.

Exhibit 9

Members

Oklahoma State Board of Pharmacy, 1999-2000

The mission of the Oklahoma State Board of Pharmacy is to protect the health, safety, and welfare of the citizens of Oklahoma by regulating and enforcing the laws regarding to the practice of pharmacy and the manufacturing, sales, distribution and storage of drugs, medicines, chemicals, and poisons.

Tom Dudley, DDS, President	Oklahoma City
Carl Lyons, R.Ph., Vice-President	Tulsa

Members:	
Jerry Allen, R.Ph.	Weatherford
Janis K. McAllister, R.Ph.	Woodward
Robert Summers, R.Ph.	Tulsa
Don Coody, R.Ph.	Oklahoma City

Exhibit 10

Supplemental FDA Response to AMA

Letter to E. Ratcliffe Anderson, Jr., M.D. Executive Vice President, CEO, AMA
from Jane E. Henney, M.D., Commissioner of Food and Drugs, FDA
August 21, 2000

E. Ratcliffe Anderson, Jr., M.D.
Executive Vice President, CEO
American Medical Association
515 North State Street
Chicago, IL 60610

Dear Dr. Anderson,

On November 3, 1999, you wrote to me seeking clarification of a FDA policy on the return of unused, sealed, and dated drugs from nursing homes or LTCFs to the dispensing pharmacies.

Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research, responded on my behalf and stated that the FDA would not object if sealed, tamper-evident, within-date medications are returned to the dispensing pharmacy by nursing homes or other LTCFs under certain specified conditions. (see Exhibit 5, this paper)

Since that response to you, we have had several inquiries from States and other interested parties. Dr. Wookcock, Mr. Baker, the Associate Commissioner for Regulatory Affairs, and I have subsequently discussed this issue and have given reconsideration to the position originally provided to you.

While we recognize the need that many senior citizens have for lower-priced prescription drugs, we believe there are competing safety considerations that must be taken into account in determining whether to allow the return and reuse of pharmaceuticals.

First and foremost are those related to the quality of the returned product and the risks to patients if the identity, strength, quality, or purity of the drugs was compromised as a result of their sale, storage, handling, return, and resale. There is a legitimate risk to patient health that could result if the quality of returned goods was compromised after initial dispensing by the pharmacists. Our modifications to the conditions you proposed in your letter, when limited strictly to manufacturer's prepackaged products, should address most of these concerns.

Another issue that does not necessarily affect patient safety but impacts patient health is drug diversion and economic fraud. Unless there are close controls regarding specific sales, shipments, and lot numbers of drugs, there is a potential for drugs to be diverted and then sold on the gray market or to have drugs already on the gray market provided to patients under this system.

In either case, we have concerns that counterfeit drugs, expired drugs, or products of otherwise inferior quality would be provided to patients. The provision that return and reuse be allowed only if the drugs are in the manufacturer's original packaging could somewhat mitigate this concern, but controls should still be assessed.

In summary, there is widespread variability in the types of drugs and the manner in which they are supplied to LTCFs. The FDA has concluded that individual States, which have direct responsibility for regulating pharmacies, nursing homes, and LTCFs, are in a better position to make a determination on a case by case basis for the protection of their citizens.

The Agency cannot support a general policy on the return of pharmaceuticals from LTCFs because of the concerns expressed above. We will continue to be vigilant in our efforts to inhibit the commerce of subpotent, compromised, or illegally diverted pharmaceuticals.

I hope that this discussion of the issues associated with return and reuse of pharmaceuticals is helpful. If you have any further questions on this matter, I would be happy to provide you with further information.

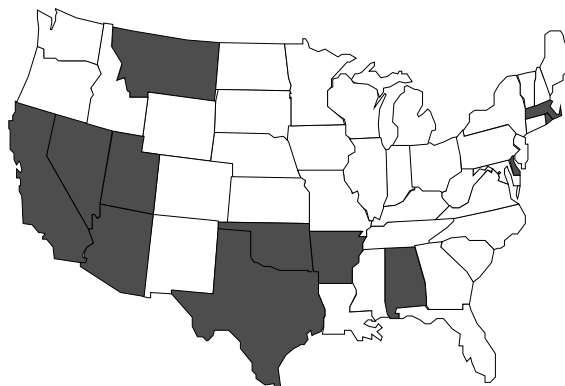
Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

Figure 1

States Not Allowing Drug Recycling in Any Form

See Table 1, Exhibit 12. Source: Medicaid Office, State of Texas

***This Issue Paper***

This study was performed by the OSU Center for Health Policy Research. The Tulsa County Medical Society was helpful in providing relevant background and supporting documents, as well as narratives explaining their state and national efforts to-date.

The methods, findings and conclusions are solely those of the Center. There is no contractual relationship between the Center and the Society. The cost of printing and distribution of the study has been borne by the TCMS to facilitate maximum statewide dissemination.

Exhibit 11

Pilot Program
HB 1130 Medication Study
 State of Oklahoma

Background

Regulations for Licensure of Nursing and Specialized Facilities require nursing facilities to establish policies and procedures for the destruction of discontinued or other unused medications within a reasonable time. To comply with this requirement nursing facilities destroy a considerable number of discontinued or unused medications on a monthly basis.

In 1997, the Oklahoma Legislature enacted House Bill 1130 which directed the Oklahoma State Board of Health in concert with the State Board of Pharmacy and the Oklahoma Health Care Authority to conduct a pilot program using anti-ulcer and antiarthritic medications to determine if the use of bubble pack units and the return and reissuance of unadulterated medications is cost-effective and administratively efficient.

Objectives

The purpose of the pilot program is to develop a system to study the number of anti-ulcer and antiarthritic medications destroyed by nursing facilities, to evaluate the costs related to these medications, and to determine the feasibility of returning the medications to the issuing pharmacist for reissue to other residents.

Method

The pilot program was planned and implemented by representatives of the Oklahoma State Department of Health, the Oklahoma Health Care Authority, and the Oklahoma State Board of Pharmacy with the assistance of nursing facility employees and consultant pharmacists.

Using a medication manifest form designed by representatives of the three agencies involved, data related to the medications in the two study groups was collected for three months. Twelve nursing facilities and their consultant pharmacists were selected to participate in the study. Facilities were selected based on the number of licensed beds, location, and the type of consultant pharmacist utilized.

Six facilities were located in urban areas of the state and six were in rural areas. One-third of the facilities were licensed for less than 70 beds, one-third were licensed within a range of 70 to 120 beds, and one-third were licensed for over 120 beds. The consultant pharmacists who assisted in the data collection were both local retail pharmacists and pharmacy consultant companies.

The nursing facilities and pharmacists were requested to destroy medications on a monthly basis for three months and to complete the medication manifest form for all anti-ulcer and antiarthritic medications destroyed. The forms were submitted to the Department of Health following each

destruction cycle. Eleven of the twelve facilities selected to participate in the study supplied the information requested. The medications used in the study included medications reimbursed by Medicaid and those purchased by private pay residents. A unit price was assigned to each medication listed on the manifest form based on data provided by the Oklahoma Health Care Authority.

These costs were used to calculate the overall cost. A reprocessing fee estimated at the current Medicaid dispensing fee of \$4.10 and administrative charges estimated at one-half the dispensing fee was deducted from the total cost to get the net cost of anti-ulcer and antiarthritic medications destroyed.

Results

The information from the medication manifest forms was sorted by name and strength of the medication. Total cost of each medication was calculated using the unit cost formula. The months of data collected demonstrated that the average cost of medications discarded per resident per month in the two categories included in the study was \$.8455 (85 cents).

Based on the total licensed beds in the state, it is estimated that the total impact statewide for a twelve month period would be \$253,500. A total Medicaid impact of \$106,470 was estimated using a 42 percent Medicaid occupancy rate in nursing facilities.

Conclusion

It was the consensus of the participants who evaluated the data, that based on this study, it is not feasible to return the medications to the pharmacy for reissue.

The total impact statewide was figured based on licensed beds rather than occupancy rate. Additional costs are likely to be incurred to maintain a system to ensure the integrity of the medications being returned. Medications returned to the pharmacy with short shelf life remaining may not in some cases be reissued by the pharmacy prior to the expiration date. These factors will reduce the net benefits of the overall effort.

List of Participants

Agency Representatives
 House Bill 1130
 Medication Study

Oklahoma State Department of Health

Evelyn Battle, Chief, Long Term Care
 Lisa Day, Director, Program Monitoring
 Linda Wilkerson, Director, Survey Division
 Ken Sisson, Health Facility Pharmacy Consultant

Oklahoma Health Care Authority

Ralph Hiatt, Pharmacy Programs Coordinator
 John Crumly, DUR Manager
 Elgene Jacobs, OBRA Coordinator

State Board of Pharmacy

Bryan Potter, Director, Oklahoma State Board of Pharmacy
 Gara Prather, Representative, Oklahoma State Board of Pharmacy

Exhibit 12

Study Report: Recycling of Prescription Drugs Long Term Care Facilities

Medicaid Office, State of Texas

Introduction

The Health and Human Services Commission formed a workgroup to study the feasibility, benefits, costs, and legal issues of recycling unused nursing home drugs. This study was mandated by legislation enacted by the 76th Texas Legislature, General Appropriations Act, Article II, Health and Human Services Commission, Rider 12.

Workgroup members include:

Geri Williams (Chair)
Health and Human Services Commission, State Medicaid Division

Curtis Burch, R.Ph. (Member)
Department of Health, Vendor Drug Program

Gay Dodson, R.Ph. (Member)
Executive Director, State Board of Pharmacy

G. Neil Libby, R.Ph., Ph.D. (Member)
Department of Human Services, Long Term Care Regulatory

Cynthia Culmo, R.Ph. (Member)
Department of Health, Division of Drugs and Medical Devices

The report of the workgroup is structured by the legislative mandate and includes:

- A) Feasibility
- B) Benefits
- C) Costs
- D) Legal Issues
- E) Recommendations

Background

The potential waste caused by destroying unused drugs prescribed for nursing home patients has been a public and legislative concern for over two decades. Continuing cost escalation of prescription drugs has promoted a re-valuation of this multifaceted issue.

The Texas Department of Public Welfare conducted the first study to project the costs associated with this policy related to Medicaid patients in 1980 (7). More recent studies were conducted in 1991, one by the Drug Use Review Program of the Texas Department of Human Services (7) and another by a University of Texas College of Pharmacy graduate student, Brian Shinavar, M.S., R.Ph. Mr. Shinavar's study included both Medicaid and non-Medicaid patients, while the studies conducted by the State Medicaid agency focused on Medicaid patients.

Each of the studies, utilizing different methodologies, concluded that medication waste through drug destruction requirements averaged approximately 4% of the total ingredient cost dispensed. Mr. Shinavar's study also stated that the 7.7% of prescriptions dispensed in the sample had

some quantity wasted. The most recent national study conducted in Massachusetts in 1992 by Paone, et al, determined the cost of medication destroyed as a percentage of medication dispensed to be approximately 6.7% (6).

The American Medical Directors Association believes that medication waste may be between 5-10% of the costs of medications dispensed in LTCFs. Studies (5,6) identifying the quantity of drugs destroyed are out-of-date, do not reflect changes in long term care, nor do they reflect changes in physician prescribing patterns.

There have been significant changes in long-term care and standard methods used for drug distribution systems have been modified. A majority of facilities now use punch cards instead of prescription vials. Physician prescribing practices and drug therapies have changed to reflect the needs of today's nursing home residents who are older, sicker, and have a higher incidence of cognitive impairment diseases. The 1991 removal of the three prescription limit by the State Medicaid program for nursing home residents raised the overall number of prescriptions per resident, but allowed physicians to prescribe reduced quantities of drugs to patients to use on a trial basis to determine the most effective drug therapy.

Legislative initiatives in 1985 and 1989 would have allowed shipment of unused drugs to foreign countries. The Texas Department of Health was unable to implement these laws because of conflict with U.S. FDA regulations.

Methodology

A member of the workgroup, G. Neil Libby, R.Ph., Ph.D., conducted an extensive literature review regarding the destruction of unused nursing home drugs. Dr. Libby conducted interviews with representatives of three pharmacy corporations with inter-state dispensing operations (7) who provided information on recycling prescriptions, as well as interviews with long term care pharmacy consultants. The government affairs office of the American Society of Consultant Pharmacists updated the workgroup on current recycling programs and pending legislation. The Executive Director of the Tulsa County Medical Society provided critical data on the status of negotiations between the State of Oklahoma and the U.S. FDA. Workgroup members analyzed this data utilizing extensive experience in the clinical and administrative aspects of long-term care drug distribution and funding.

The workgroup surveyed states to determine which states had recycling programs in place. Table 1- Exhibit 12 (next page) represents responses from states on their experience.

Feasibility

Current FDA guidelines (4,9) restrict the recycling of discontinued drugs to medications returned in the original manufacturers' packages. This FDA policy significantly reduces the number of unused drugs eligible for recycling and severely limits the potential cost-benefits of a recycling program.

A number of states currently have pending legislation and pilot programs (1,2). States have implemented programs that recycle unused nursing home drugs to the originating pharmacy as well as recycling these drugs to indigent health care programs. It should be noted that these state programs are operating in conflict with current federal law.

Mr. Brad Lanham, R.Ph. (Pharmerica) and Mr. Tim Vordenbaumen, R.Ph. (American Pharmaceutical Services), representing the Coalition of Texas Long Term Care Pharmacies, provided the workgroup a perspective of the pharmacy industry's concerns regarding the recycling of nursing home drugs. The obstacles and concerns related to recycling nursing home drugs identified in their letter to the workgroup were thoroughly addressed in workgroup discussions.

Benefits

The benefits of instituting a recycling system in LTCFs include the possibility of an overall decrease in drug costs for the state and the removal of costs associated with various LTCF facility administrative activities related to drug destruction. Examples of activities that would be impacted include:

(1) An effective recycling program could reduce the time spent by directors of nursing administrators and consultant pharmacists destroying unused drugs. In an average nursing home, these professionals spend approximately 40 hours annually in direct drug destruction activities. Additional administrative requirements to document and track recycled drugs might reduce the timesaving.

(2) Expanding restrictions for drug destruction by the EPA have resulted in many facilities contracting with disposal companies for drug destruction. A recycling program could reduce this expense.

(3) Texas DHS surveys indicate discontinued drugs are a primary source of drug thefts in nursing homes. An effective recycling program could improve drug security and accountability, thus possibly reducing pilferage.

Costs

There is a wide spectrum of opinion on the estimated value of drugs destroyed annually by nursing homes in Texas. Within the workgroup, estimates of the value of these drugs ranged from \$6-20 million. The Louisiana Department of Health and Hospitals estimates \$2-5 million in unused drugs are destroyed annually while in Oklahoma, estimates range from \$3-10 million annually. An effective recycling program would be complex with substantial administrative costs; however, information is not readily available to determine the cost effectiveness. Costs associated with implementing a recycling system include the following issues:

(1) Pharmacists would require a reimbursement fee for reprocessing returned prescriptions. The transport, storage, record-keeping, and re-labeling of recycled prescriptions would require pharmacist resources. An effective system to credit returned prescription to multiple payers would be

complex and costs would be significant. Reimbursement fees would reduce net cost savings.

(2) The Medicaid State Vendor Drug Program projects collection of over \$39 million in fiscal year 2000 in manufacturer rebates from nursing home drug expenditures. The Medicaid State Vendor Drug Program would be required to redesign the existing rebate system and offer reassurance that all recycled drug claims were reversed and credited before drug manufacturers were rebilled. The rebate system generates extensive cost savings for Texas and must not be jeopardized by a recycling program. Serious consideration must be given to the possible impact on the rebate system. Some drug manufacturers could dispute rebate payments and reduce funds that are relied upon as a method of finance for the Medicaid State Vendor Drug Program.

(3) The Medicaid State Vendor Drug Program would incur administrative costs in monitoring the pharmacy record keeping and storage. The Texas Department of Health Drug and Medical Devices division would incur administrative costs associated with monitoring reprocessing and relabeling of recycled prescriptions.

(4) The Texas DHS, Long Term Care Regulatory would have to expend resources for the onsite inspection of unused drug storage marked for recycling to insure proper environmental and security standards.

(5) Nursing homes would incur costs associated with handling, record keeping, and storage of unused drugs marked for recycling.

Legal Issues

(A) Changes to existing state laws and regulations would be required to allow recycling of prescription drugs, including:

- 1) Texas Food, Drug, and Cosmetic Act, Chapter 431, Health and Safety Code, Section 431.021 (W);
- 2) Texas Pharmacy rules, 22 TAC Part 15, Section 29.8, Return of Prescription Drugs;
- 3) Long Term Care Facilities Requirements for Licensure and Medicaid Certification 19.1504 (H);

(B) The following federal laws and policies impact directly upon recycling prescription drugs for LTCFs:

- 1) FDA Compliance Policy Guide;
- 2) Federal Prescription Drug Marketing Act of 1987;
- 3) Federal Food, Drug, and Cosmetic Act;
- 4) 21 Code of Federal Regulations, Part 200

A February 25, 2000, opinion letter (4) from the Center for Drug Evaluation and Research, FDA, to the AMA, states that recycling is allowed if the guidelines in the AMA Council on Scientific Affairs Report of February 1, 1997, are followed, along with five specific additional CDER requirements. Most important is that the CDER opinion letter specifies approval only for the recycling of medications that have been dispensed in the original manufacturers' packaging.

C) A policy clarification letter from Jane E. Henney, M.D., Commissioner, FDA, was released on August 11, 2000. In summary, the FDA stated it could not support a general policy on the return of pharmaceuticals from LTCFs citing various patient health and safety concerns. However, the FDA concluded that individual states, which have direct responsibility for regulating pharmacies, nursing homes, and LTCFs, would be allowed to make individual decisions as to whether a drug recycling program, limited strictly to manufacturers prepackaged products, would be feasible within the close controls described in the letter.

Conclusion

With the receipt of the FDA's policy clarification on recycling nursing home drugs, it does not appear to be cost effective for the State of Texas to implement a recycling program. The policy clarification stipulates that only manufacturer's prepackaged products are allowed in a recycling program. This restriction prevents the legal recycling of an estimated 80% of unused nursing home medications. However, it would be beneficial for the State of Texas to have current data on drug waste in LTCFs to determine a true cost/value analysis.

Recommendation

The workgroup recommends the State of Texas find a more comprehensive research study on the topic of recycling unused nursing home medications. This study would provide the additional information that is essential for performing a cost/value analysis. The workgroup recommends the study should:

- (1) Determine an accurate estimate of the value of unused drugs destroyed annually including a breakdown by packaging and dosage forms;
- (2) Evaluate other states experience to determine costs for development and maintenance of recycling programs;
- (3) Identify selected clinical, administrative, and technological interventions that would reduce the incidence of medication waste and the feasibility of implementing these systems.

This recommendation, if implemented, would serve as an essential preliminary step in determining the feasibility of establishing a cost-effective prescription-recycling program on Texas.

References

1. Recycling of Unused Drugs Proposed, Tulsa World; Tulsa, OK; 01-30-00.
2. Drug Recycling Program Needed, Advocate; Baton Rouge, LA; 02-25-00.
3. Redirecting Unused Meds Could Save Millions. American Medical News; 04-03-00.
4. Informal opinion letter. FDA to AMA; 02-25-00.
5. Shinavier BD, Kirk KW. Medication waste in selected central Texas LTCFs under the same corporate ownership. Consultant Pharmacist. 1992; 7:415-422.
6. Peone RP, Vogenberg FR, Caporello E, et al. Medication destruction and waste management in LTCFs. Consultant Pharmacist. 1996; 11:32-40.
7. Texas DHS studies; 1980, 1991.
8. Guidty, Tom, Pharm. D. - Sunscript Pharmacy Corporation; Dasher, Tony, Pharm. D. - American Pharmaceutical Services; McCullough, Steven, R.Ph. - Personacare of San Antonio
9. Policy clarification letter. FDA to E. Ratcliffe Anderson, Jr., M.D., AMA. 08-11-00.

Table 1 - Exhibit 12
State Activity Summary
 Medicaid Office, State of Texas, 2000

Allow: Allow recycling of drugs dispensed to patients in nursing homes? * indicates allowed with notable restrictions.
Since: If yes, how long has it been allowed? **Resold:** Are the drugs allowed to be resold through a pharmacy? * indicates resold with restrictions.

<u>STATE</u>	<u>ALLOW</u>	<u>SINCE</u>	<u>RESOLD</u>
Alabama	No		
Alaska	Yes*	Unknown	Yes
Alaska	----		
Arizona	No		
Arkansas	No		
California	No		
Colorado	Yes	Unknown	Yes*
Connecticut	Yes	1998	Yes
Delaware	No		
Florida	Yes	Unknown	Yes
Georgia	Yes*	1997	Yes*
Idaho	Yes*	1998	Yes
Illinois	Yes*		
Indiana	Yes	1981	Yes
Iowa	Yes*	Unknown	Yes
Kansas	Yes*	Unknown	NH Only
Kentucky	Yes	Unknown	Yes
Louisiana	Yes	2000	No
Maine	Yes	1980	Yes
Maryland	Yes	1977	Yes
Massachusetts	No		
Michigan	Yes	1985	Yes*
Minnesota	Yes*	Unknown	Yes
Mississippi	Yes	Unknown	Yes*
Missouri	Yes	Unknown	Yes*
Montana	No		
Nebraska	Yes	1999	Yes
Nevada	No		
New Hampshire	Yes	1979	Yes
New Jersey	Yes	Unknown	Yes
New Mexico	Yes	1988	Yes*
New York	Yes	1980	No
North Carolina	Yes	1975	Yes
North Dakota	Yes	1997	Yes
Ohio	Yes	Unknown	Yes*
Oklahoma	No		
Oregon	Yes	Unknown	Yes
Pennsylvania	Yes	Unknown	Yes*
Rhode Island	No		
South Dakota	Yes	Unknown	Yes
South Carolina	Yes	Unknown	Yes*
Tennessee	Yes	Unknown	Yes*
Texas	No		
Utah	No		
Vermont	----		
Virginia	Yes	Unknown	Yes
Washington	Yes	1994	Yes
West Virginia	Yes	Unknown	Yes
Wisconsin	Yes	Unknown	Yes
Wyoming	Yes	Unknown	Yes*