

CENTER FOR HEALTH POLICY RESEARCH

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

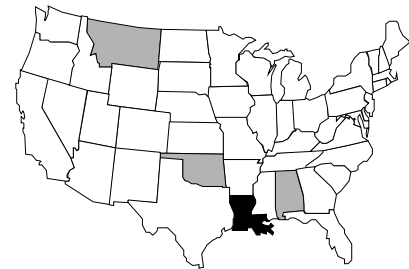


HEALTH & MEDICINE ISSUE PAPER



• A 50-STATE SURVEY •

PRESCRIPTION DRUG RE-USE POLICIES



Introduction

This paper supplements our Health Policy Brief: Prescription Medicines & Nursing Homes, A Problem - A Solution, published in September 2000. That brief addressed the problem of prescription drug waste in nursing homes. At issue was:

Oklahoma nursing homes and other health care organizations are legally required to destroy millions of dollars of unused prescription medications. Medically indigent Oklahomans may not receive necessary medications because of an individual inability to pay, or the inability of agencies to purchase medications for them. This contradiction would not matter if the wasted sums were small. They are not.

New Information

In that brief, it was reported that there are 36 states with restricted prescription drug re-use policies, and 12 states without such policies (Medicaid Office, State of Texas, 2000). We did not have sufficient information at that time, however, to determine whether those states claiming recycling programs had the same purpose/intent for re-use as is being proposed in Oklahoma HB1297.

Upon reflection, we believe the initial information to be potentially misleading and not in the proper context of HB1297. It seems to suggest that HB1297-like programs exist in many states. They do not.

Since that time, we constructed a survey with specific text from HB1297 (see text box to right, this page). We administered the survey twice:

- February 2001 by contacting the American Drug Utilization Review Society (ADURS) and receiving responses from state Medicaid agencies and Public Program Pharmacists via mail
- April 2001 by contacting the Boards of Pharmacy of every state via phone and fax.

We asked if their state allowed recycling as stated in the text. The numbers of positive responses to this survey did not correlate with those previously reported. The responses and conclusions derived from this effort are at Tables 1-3 on page 2.

Upon further analysis, we believe that three states, Louisiana, Montana and Alabama have, or are in the process of legislating for, a recycling program that is similar to what Oklahoma is trying to achieve.

The specific guidelines/legislation of each of these states follows.

This Survey

The survey consisted of the five questions below, to be answered after reading the following language from Oklahoma House Bill 1297 (2001 Legislature):

"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 and dangerous substances ... may be transferred from nursing homes to repositories established for the purpose of distributing the medication to Oklahoma residents who are medically indigent ... that participation in the program is voluntary on a county-by-county basis or by multi-county regions ..."

1. Does YOUR state allow for the redistribution of prescription drugs as outlined in HB1297? (Yes, No, Not Sure)
2. If you answered YES to #1, what is the legal authority under which such action is sanctioned? (State Statute, Pharmacy Board Regulation, State Health Department Regulation, Other authority (to be listed), Don't know)
3. If you answered YES to #1, will you help furnish us (upon our request) a copy and/or citation of the legal authority? (Yes, No)
4. If you answered YES to #1, will you agree to provide us (upon our request) appropriate contacts at THREE organizations that routinely reuse the prescription drugs? (Yes, No)
5. May we contact you to gather additional information? Or so that you may direct us to a more appropriate individual/organization in your state? (Yes, No)

LORI RYAN, RESEARCH ASSISTANT

**Table 1
Pharmacy Board Responses
April 2001**

Does YOUR state allow for the redistribution of prescription drugs as outlined in HB1297? (Yes, No, Not Sure)

Alabama	No (Pending)
Alaska	No Response
Arizona	No
Arkansas	No
California	No Response
Colorado	No
Connecticut	No
Delaware	No
D.C.	No
Florida	No Response
Georgia	No
Hawaii	No
Idaho	No
Illinois	No
Indiana	Not Sure
Iowa	No
Kansas	Yes
Kentucky	No Response
Louisiana	Yes
Maine	No Response
Maryland	No
Massachusetts	No
Michigan	No
Minnesota	No
Mississippi	No
Missouri	No
Montana	Yes (Pending)
Nebraska	No Response
Nevada	No
New Hampshire	No
New Jersey	No Response
New Mexico	No
New York	No
North Carolina	Yes
North Dakota	No
Ohio	No
Oklahoma	No (Pending)
Oregon	No
Pennsylvania	No
Rhode Island	No
South Carolina	No
South Dakota	No
Tennessee	No
Texas	No
Utah	No
Vermont	No Response
Virginia	No
Washington	No
West Virginia	No Response
Wisconsin	No
Wyoming	Yes

**Table 2
Pharmacy Board Respondent
Comments, April 2001**

Alabama	Legislation Pending (HB27 included)
Florida:	Non-Controlled unit doses may be returned from nursing homes to stock.
Hawaii:	Current laws allow for prescription drugs to be returned to the pharmacy to be redispensed or redistributed. Legislation Pending (HB644, HD1, SD1) proposing to allow pharmacies & institutional facilities to donate drugs to the needy.
Idaho	State law does not allow for the redistribution of prescription drugs. Nursing homes may return blister pak medications or unit dose medications to the provider pharmacy only as long as Board Guidelines are followed (rule 156.05 included).
Illinois	In response to Question 5, noted that there is no further information at this time.
Kansas	If drugs are kept in a controlled environment. Included the proposal & it appears to allow for a return to the pharmacy for reimbursement. For further information, contact Social & Rehabilitation Services.
Louisiana	Included regulation
Michigan	May contact for a referral to a more appropriate contact.
Missouri	Included regulation
Montana	New legislation pending Governor's signature. The enabling statute passed, rules are pending - ask after October 1, 2001. Included SB288.
Nevada	To avoid contamination or product tampering, allow return of manufacturer's unit dose packages only for credit.
New York	Allows for return for credit & redistribution to another nursing home patient.
North Carolina	In the US, everything not prohibited is permitted. There is no such prohibition.
North Dakota	Attached a copy of regulation on return of drugs in nursing homes (can be returned to the pharmacy from which they were dispensed.)
Ohio	Ohio had similar legislation introduced last year. However, it did not pass. Not sure if it will be re-introduced this session of the General Assembly.
Oklahoma	HB1297 Pending in Legislature
Pennsylvania	Did not return survey, but faxed Section 5 of the Pharmacy Act.
Wyoming	May return to pharmacy who issued for resale.

**Table 3
ADURS Responses
February 2001**

Does YOUR state allow for the redistribution of prescription drugs as outlined in HB1297? (Yes, No, Not Sure)

Alabama	No
Alaska	No Response
Arizona	No Response
Arkansas	No
California	No
Colorado	No
Connecticut	No Response
Delaware	No
D.C.	No Response
Florida	No Response
Georgia	No Response
Hawaii	No
Idaho	Yes
Illinois	No Response
Indiana	Yes
Iowa	No Response
Kansas	Not Sure
Kentucky	No Response
Louisiana	Yes
Maine	No
Maryland	No
Massachusetts	No Response
Michigan	No Response
Minnesota	No Response
Mississippi	No
Missouri	No
Montana	No Response
Nebraska	No
Nevada	No
New Hampshire	No Response
New Jersey	No
New Mexico	No
New York	No
North Carolina	No Response
North Dakota	No Response
Ohio	No Response
Oklahoma	No
Oregon	No Response
Pennsylvania	No Response
Rhode Island	No Response
South Carolina	No
South Dakota	No
Tennessee	No Response
Texas	No
Utah	No
Vermont	No Response
Virginia	No
Washington	No Response
West Virginia	No
Wisconsin	No
Wyoming	No

Louisiana

Louisiana currently allows for the reuse of prescription drugs by Pharmacy Board Regulation as long as the following conditions are met:

- [Drugs may be returned] in facilities licensed by the Louisiana Department of Health and Hospitals where United States Pharmacopeia (USP) storage requirements can be assured, legend drugs, except controlled substances, dispensed in unit dose or in individually sealed doses may be transferred to a provisional permitted pharmacy for relabeling and dispensing to the indigent, free of charge, pursuant to a valid prescription order.
- The pharmacist-in-charge (PIC) of the provisional permitted pharmacy shall be responsible to determine the suitability of the product for reuse.
- No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
- A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
- No product shall be redispensed more than one time.
- Pursuant to a voluntary agreement between a facility licensed by the Louisiana Department of Health and Hospitals and a pharmacy holding a provisional permit from the Louisiana Board of Pharmacy, legend drugs, except controlled substances, may be transferred from the facility to the pharmacy provided the following procedures are satisfied.
- The physical transfer shall be accomplished by a person authorized to do so by the provisional permitted pharmacy.
- The patient from whom the prescription medication was obtained shall document their consent for the donation; the consent shall be maintained on file at the facility.
- The patient's name, prescription number, and any other identifying marks, shall be obliterated from the packaging prior to removal from the facility.
- The drug name, strength, and expiration date shall remain on the medication package label.
- An inventory list of the drugs shall accompany the drugs being transferred; at a minimum, the list shall contain the medication name, strength, expiration date, and quantity.
- Expired drugs shall not be transferred; personnel designated by the facility shall destroy them on-site.

(Louisiana Pharmacy Board Regulation §3517)

Montana

Montana has passed new legislation that is pending the Governor's signature (see page 4 for full text)

The key points of interest to Oklahoma in SB288 are that it requires the Board of Pharmacy, in consultation and cooperation with the Department of Public Health and Human Services to create a program for the donation of prescription drugs collected from long-term care facilities to provisional community pharmacies offering drugs to certain low-income persons.

A "Provisional Community Pharmacy" is defined as the practice of pharmacy at a site that has been approved by the board, including but not limited to federally qualified health centers (defined in 42 CFR 405.2401) where prescription drugs are dispensed to appropriately screened, qualified patients. In addition, the bill proscribes that long-term care facilities will delete identifying information from donated prescription drugs and the long-term care patients and facilities donating prescription drugs will be immune from liability.

Alabama

Alabama currently has legislation pending (see page 4 for full text) that would allow licensed nursing homes and hospitals to distribute unused prescription medications to certain charitable pharmacies.

It is interesting to note that Alabama's HB27 mirrors the key points, word for word, of Louisiana Pharmacy Board Regulation §3517, the only exception being the use of "Charitable Pharmacy" in lieu of "Provisional Permitted Pharmacy".

A Charitable Pharmacy is defined as a place licensed by the Alabama State Board of Pharmacy which is operated on a nonprofit basis and in which drugs are compounded or dispensed and shall include any place whose title may imply the compounding or dispensing of drugs.

Other States

As can be seen in Table 3, Idaho and Indiana, and in Table 1, Kansas, North Carolina and Wyoming also answered yes to question #1. It is our belief, based partly on comments offered by the states, that they do not allow for reuse as specified in Oklahoma HB1297, but rather allow for some form of recycling within a pharmacy or other controlled unit for credit/reimbursement purposes.

Concerns

There are legitimate concerns regarding the reissue of prescription drugs, including but not limited to:

- ownership of the drugs
- who has the authority to re-use
- patient confidentiality
- the cost of transferring the drugs
- drug expiration dates and liability.

Summary

Comparing the data collected for our first issue paper in September 2000 on prescription medicines & nursing homes with the new information obtained in April 2001, it can be seen that there is a wide disparity between the states that reported allowing the reuse of prescription drugs.

Closer examination reveals that this can probably be attributed to an initial misunderstanding of the specific language regarding the intended purpose of reuse.

Looking at the states that do allow, or are legislating to allow (Louisiana, Montana and Alabama) the reuse of prescription drugs from nursing homes for the medically indigent, it can be seen that the aforementioned concerns can be addressed with efficient use of regulations and resources.

Cost Estimates of Unused Drugs in Nursing Homes

(Previous Health and Medicine Letter, September 2000)

	Oklahoma	National
NH Patient Census	25,000	1,400,000
Value of Unused Drugs	\$2.3-7 M	\$73-378 M

**Oklahoma Nursing Homes
Estimated Mix of Destroyed Medications**

Category	Percent
Antibiotics	25%
Hypertensives/Cardiac	25%
Analgesics	20%
Gastrointestinal	15%
Diabetes	10%
Other	5%
Total	100%

**Montana
Senate Bill 288**

INTRODUCED BY C. CHRISTIAENS, WATERMAN, MCCARTHY

AN ACT REQUIRING THE BOARD OF PHARMACY TO CREATE A PROGRAM FOR THE DONATION OF PRESCRIPTION DRUGS BY LONG-TERM CARE FACILITIES TO PROVISIONAL COMMUNITY PHARMACIES OFFERING DRUGS TO CERTAIN LOW-INCOME PERSONS; REQUIRING THE BOARD OF PHARMACY TO ADOPT RULES; PROVIDING DEFINITIONS; REQUIRING A LONG-TERM CARE FACILITY DONATING DRUGS TO DELETE PATIENT IDENTIFICATION INFORMATION FROM THE PRESCRIPTION DRUG CONTAINER; PROVIDING FOR IMMUNITY FROM SIMPLE NEGLIGENCE FOR LONG-TERM CARE FACILITIES AND PATIENTS DONATING PRESCRIPTION DRUGS; AND PROVIDING EFFECTIVE DATES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Department of public health and human services and board of pharmacy to create program for donation of unused prescription drugs — rulemaking required. (1) The board of pharmacy shall, in consultation and cooperation with the department of public health and human services, create a program for the donation of prescription drugs collected from long-term care facilities to qualified patients.

(2) For the purposes of the program created pursuant to subsection (1), prescription drugs, except those drugs defined as a dangerous drug in 50-32-101 or a drug designated as a precursor to a controlled substance in 50-32-401, unneeded by a resident or former resident of a long-term care facility may be donated by the long-term care facility to a provisional community pharmacy that provides or may provide prescription drugs to individuals who are qualified patients for transfer free of charge or at a reduced charge to those individuals.

(3) This section does not amend or otherwise change the law applicable to the prescribing of prescription drugs, the sale of those drugs, or the licensing of long-term care facilities or pharmacies.

(4) The board of pharmacy shall adopt rules to implement [sections 1 through 3]. The rules must address the subjects of collection and receipt of donated prescription drugs from residents of long-term care facilities, keeping of those drugs within the long-term care facility, transfer of the drugs to provisional community pharmacies, which pharmacies may be considered provisional community pharmacies that may sell or give the drugs to others, and the price for which the drugs may be sold. In adopting the rules, the board of pharmacy shall consider the ability of persons to pay for the drugs and the existence and operation of similar programs in other states.

(5) As used in [sections 1 through 3], the following definitions apply:

(a) "Long-term care facility" has the meaning provided in 50-5-101.

(b) "Provisional community pharmacy" means the practice of pharmacy at a site that has been approved by the board, including but not limited to federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(c) "Qualified patients" mean persons who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.

Section 2. Long-term care facilities to delete identifying information from donated prescription drugs. A long-term care facility donating a prescription drug pursuant to the program created under [sections 1 through 3] shall delete from the container in which that drug is held any information by which the long-term care facility resident or former resident for whom the drugs were prescribed may be identified.

Section 3. Immunity for long-term care patients and facilities donating prescription drugs. A resident or former resident of a long-term care facility and the long-term care facility donating a prescription drug as part of the program created pursuant to [sections 1 through 3] are not liable for simple negligence in the donation of a drug if the requirements of [sections 1 through 3] and the rules implementing [sections 1 through 3] have been complied with.

Section 4. Codification instruction. [Sections 1 through 3] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 1 through 3].

Section 5. Effective dates. (1) Except as provided in subsection (2), [this act] is effective October 1, 2001.

(2) [Sections 1 (4) and 4 and this section] are effective on passage and approval.

**Alabama
House Bill 27**

SYNOPSIS: Currently unused prescription medications must be destroyed by nursing homes and hospitals and may not be distributed to charities. This bill would allow licensed nursing homes and hospitals to distribute unused prescription medications to certain charitable pharmacies.

A BILL TO BE ENTITLED AN ACT

To allow licensed nursing homes and hospitals to distribute unused prescription medications to certain charitable pharmacies.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. As used in this act, the following terms shall have the following meanings:

(1) CHARITABLE PHARMACY. A place licensed by the Alabama State Board of Pharmacy which is operated on a nonprofit basis and in which drugs are compounded or dispensed and shall include any place whose title may imply the compounding or dispensing of drugs.

(2) DISPENSE. To sell, distribute, leave with, give away, dispose of, deliver, or supply a drug to the ultimate user or his or her agent.

(3) DRUGS. All medicinal substances, preparations, and devices recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment, or prevention of disease and all substances and preparations other than food intended to affect the structure or any function of the body.

(4) HOSPITAL. An institution for the care and treatment of the sick and injured licensed by the Alabama State Board of Health and authorized to be entrusted with the custody of drugs and medicines, the professional use of such drugs and medicines being under the direct supervision of a medical practitioner or pharmacist.

(5) LEGEND DRUG. Any drug, medicine, chemical or poison bearing on the label the words, "caution, federal law prohibits dispensing without prescription," or similar wording indicating that such drug, medicine, chemical or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(6) MEDICAL PRACTITIONER. Any physician, dentist, or any other person authorized by law to treat, use, or prescribe medicine and drugs for sick and injured human beings in this state.

(7) NURSING HOME. Any institution or facility defined as such for licensing purposes under state law.

(8) PHARMACIST. Any person licensed by the Alabama State Board of Pharmacy to practice the profession of pharmacy in the State of Alabama and whose license is in good standing.

Section 2. Drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or redispensing by any charitable pharmacy after the prescription drugs have been removed from the pharmacy premises where they were dispensed except under the following circumstances:

(1) In a hospital with a licensed pharmacy on-site, prescription drugs may be returned to the pharmacy in accordance with good professional practice standards.

(2) In nursing homes or hospitals where United States Pharmacopoeia storage requirements may be assured, legend drugs, except controlled substances, dispensed in unit dose or in individually sealed doses may be transferred to a charitable pharmacy for relabeling and dispensing to charitable pharmacies, free of charge.

The pharmacist of the charitable pharmacy shall be responsible for determining the suitability of the product for reuse. No product where integrity may not be assured shall be accepted for redispensing by the pharmacist. A redispensed prescription medication shall be assigned the expiration date stated on the package. No product shall be redispensed more than one time.

Pursuant to a voluntary agreement between a nursing home or hospital and a charitable pharmacy, legend drugs, except controlled substances, may be transferred from the nursing home or hospital to the charitable pharmacy if the following procedures are satisfied:

(1) The physical transfer shall be accomplished by a person authorized to do so by the charitable pharmacy.

(2) The patient from whom the prescription drug was obtained shall document his or her consent for the donation and the consent shall be maintained on file at the nursing home or hospital.

(3) The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to removal from the nursing home or hospital.

(4) The name, strength, and expiration date of the prescription medication shall remain on the medication package label.

(5) An inventory list of the prescription drugs shall accompany the drugs being transferred, which list, at a minimum, shall contain the medication name, strength, expiration date, and quantity.

(6) Expired prescription drugs shall not be transferred and personnel designated by the nursing home or hospital shall destroy them on-site.

Section 3. This act shall become effective on the first day of the third month following its passage and approval by the Governor, or its otherwise becoming law.