



# **Louisiana Board of Pharmacy**

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Response

to

HCR 292 of 2004 Louisiana Legislature

Recycling of Unused Previously Dispensed Prescription Drugs

Submitted

April 20, 2005

## Preface

Representative John Labruzzo authored HCR 292 of the 2004 Louisiana Legislature [**Appendix A**]; the resolution requested the Department of Health and Hospitals (DHH) to research and study the implementation of a recycling method for unused prescription drugs. In his August 31, 2004 letter to the Board, DHH Undersecretary Charles Castille requested the Board of Pharmacy to assume a leadership role in the project. The Board invited Representative Labruzzo to its November 17, 2004 meeting to outline his desired outcomes for the project. During that meeting, Representative Labruzzo indicated he had acquired a better understanding of some of the unique aspects of the closed distribution system for prescription drugs, as well as a better understanding of some of the challenges to ensuring the integrity of drug products proposed for recycling. Finally, he requested the Board to consider enabling the donation of unused prescription drugs to pharmacies located in penal institutions.

## Current Authority for Donation of Prescription Drugs

The legislature first authorized the donation of unused previously dispensed prescription drugs in 2001. Act 811 of the 2004 Legislature amended the original language to expand the sources of donations. The Louisiana Pharmacy Practice Act, specifically at R.S. 37:1226.2 [**Appendix B**], permits the donation of unused previously dispensed prescription drugs to certain kinds of pharmacies known as charitable pharmacies. These pharmacies may then re-label and dispense these drugs to their qualified indigent patients, free of charge.

## Safety Considerations

In order to ensure the integrity of the drug products to be re-dispensed, the

statute places certain limitations on the nature and packaging of drugs that may be accepted for re-dispensing. Further, the pharmacist is required to ascertain that donated drugs are not misbranded or adulterated and are safe to dispense.

Misbranded drugs are products whose labeling is false or misleading or does not bear an accurate statement of the contents. Examples of misbranded products would include partially used multi-dose containers (ointments, inhalers, etc.) as well as counterfeit products. By restricting donations to drug products whose original packaging is intact, the pharmacist can achieve some level of assurance that the drug product is, in fact, what the label indicates.

Adulterated drugs are contaminated products with foreign or harmful materials, or those which fail to meet federal safety, quality, and/or purity standards. Most contaminated products are detectable by the human eye without mechanical assistance – these include such items as hair or other fibers and foreign materials such as glass, metal, or plastic. What is usually not detectable without mechanical assistance is deterioration due to extremes in temperature and/or humidity. The United States Pharmacopeia (USP) contains the official standards for drug products. The USP standard for the storage of non-refrigerated drug products requires a '*controlled room temperature*' of 66° to 77 °F and a '*dry place*' not to exceed 40% humidity. Drugs stored in higher temperatures and/or humidity are subject to deterioration; whether the deteriorated products are simply ineffective or perhaps harmful varies by drug product and is not always predictable. Without knowledge of the conditions under which a previously dispensed drug product has been stored, a pharmacist may be unable to ascertain that a drug product is safe for re-dispensing.

### Proposal for Donation of Drugs to Pharmacies in Penal Institutions

Using the same safeguards currently in place for the donation of certain drugs to charitable pharmacies, the Board has constructed a proposal to allow donors to direct their donations to either charitable pharmacies or pharmacies in penal institutions.

Representative Labruzzo has offered that proposal in the form of HB 558 [**Appendix C**].

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Regular Session, 2004

HOUSE CONCURRENT RESOLUTION NO. 292

BY REPRESENTATIVE LABRUZZO

**A CONCURRENT RESOLUTION**

To urge and request the Department of Health and Hospitals to establish a study commission to research and study the implementation of a recycling method for unused prescription drugs.

WHEREAS, the citizens of the state of Louisiana are issued prescriptions for drugs in order to treat their medical conditions and ailments; and

WHEREAS, these prescription drugs frequently are ineffective in the treatment of the patient; and

WHEREAS, the patient then ceases using the medication and the full quantity of the medication is not depleted prior to expiration; and

WHEREAS, the prescription drugs are contained in their original sealed and tamper-evident packaging; and

WHEREAS, there then exists unused, unexpired prescription medications which are discarded by the patients; and

WHEREAS, these medications could be effective in the treatment of other patients; and

WHEREAS, these drugs could be recycled and re-dispensed before their expiration dates; and

WHEREAS, a prescription drug recycling program may provide a cost-effective alternative to the citizens of the state of Louisiana.

THEREFORE, BE IT RESOLVED that the Legislature of Louisiana does hereby urge and request the Department of Health and Hospitals to establish a study commission to research and study the implementation of a recycling method for unused prescription drugs.

BE IT FURTHER RESOLVED that a copy of this Resolution be transmitted to the secretary of the Department of Health and Hospitals and that the department report its findings and recommendations to the Legislature of Louisiana prior to the convening of the 2005 Regular Session.

**TITLE 37 – PROFESSIONS AND OCCUPATIONS**

**CHAPTER 14 – PHARMACY PRACTICE ACT**

\* \* \*

**§1226.2. Prescription drug returns, exchanges, and redispensing; donation requirements; authority to promulgate rules; limitation of liability**

A. All drugs dispensed on prescription to a patient shall be accepted for return, exchange, or redispensing by a charitable pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed including but not limited to:

- (1) In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy in accordance with good professional practice standards.
- (2) Any person, including a drug manufacturer, hospital, health care facility, or governmental entity may donate prescription drugs to a charitable pharmacy for relabeling and dispensing to the indigent, free of charge, pursuant to a valid prescription order.

B. Donations of prescription drugs to a charitable pharmacy are subject to the following requirements:

- (1) The charitable pharmacy may accept only those drugs in their original sealed and tamper-evident packaging; except that drugs packaged in single-unit doses may be accepted and dispensed when the outside packaging is opened if the single-unit dose packaging is intact.
- (2) The pharmacist in charge of the charitable pharmacy shall determine if the drug is not adulterated or misbranded and is safe to dispense. No product where the integrity of the medication cannot be assured shall be accepted for redispensing by the pharmacist of the charitable pharmacy.
- (3) The donor shall execute a form stating the donation of the drugs. The pharmacist shall retain that form along with other acquisition records.
- (4) The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to redispensing the medication to another patient.
- (5) The drug name, strength, and expiration date shall remain on the medication package label. The redispensed medication shall be assigned the expiration date stated on the package.
- (6) Expired drugs accepted by a charitable pharmacy shall not be redispensed.
- (7) The charitable pharmacy shall comply with all state and federal laws regarding controlled

substances.

(8) No drug dispensed through a charitable pharmacy shall be eligible for reimbursement from the Medicaid Pharmacy Program.

C. The board shall have the authority to promulgate rules and regulations in accordance with the Administrative Procedure Act for the purpose of administering the provisions of this Section.

D. (1) No person, including a drug manufacturer, health care facility, or governmental agency who donates prescription drugs to a charitable pharmacy, as well as the charitable pharmacy, any pharmacist who originally dispensed the donated prescription drugs, any pharmacist dispensing donated prescription drugs, or the board of pharmacy shall be subject to any professional disciplinary action, criminal prosecution, liability in tort or other civil action for injury, death, or loss to person or property related to the donating, accepting, or dispensing of donated prescription drugs.

(2) No pharmaceutical manufacturer shall be liable for any claim or injury arising from the transfer of any prescription drug pursuant to the provisions of this Section, including but not limited to liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

E. For purposes of this Section “charitable pharmacy” means the practice of a pharmacy at a site where prescriptions are dispensed by a charitable organization free of charge to appropriately screened and qualified patients.

*(Added by Act 811 of 2004 Louisiana Legislature, effective August 15, 2004)*

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

DRUGS/PRESCRIPTION: Provides relative to drug returns to penal institutions

1 AN ACT

2 To amend and reenact R.S. 37:1226.2 (A)(introductory paragraph) and (2), (B)(introductory

3 paragraph) and (1), (6), (7), and (8), and (D)(1) and to enact R.S. 37:1226.2(F),

4 relative to prescription drug returns, exchanges, and redispensing; to allow penal

5 institutions to receive donated medications for redispensing to individuals in its

6 facility; and to provide for related matters.

7 Be it enacted by the Legislature of Louisiana:

8 Section 1. R.S. 37:1226.2(A)(introductory paragraph) and (2), (B)(introductory

9 paragraph) and (1), (6), (7), and (8), and (D)(1) are hereby amended and reenacted and R.S.

10 37:1226.2(F) is hereby enacted to read as follows:

11 §1226.2. Prescription drug returns, exchanges, and redispensing; donation

12 requirements; authority to promulgate rules; limitation of liability

13 A. All drugs dispensed on prescription to a patient shall be accepted for

14 return, exchange, or redispensing by a charitable pharmacy or a penal institution

15 pharmacy after such drugs have been removed from the pharmacy premises where

16 they were dispensed including but not limited to:

17 \* \* \*

18 (2) Any person, including a drug manufacturer, hospital, health care facility,

19 or governmental entity may donate prescription drugs to a charitable pharmacy for

20 relabeling and dispensing to the indigent, free of charge, or to a penal institution

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1 pharmacy for relabeling and dispensing to a prisoner of that institution pursuant 1 to

2 a valid prescription order.



3 B. Donations of prescription drugs to a charitable pharmacy or a penal  
4 institution pharmacy are subject to the following requirements:

5 (1) The charitable pharmacy or a penal institution pharmacy may accept only  
6 those drugs in their original sealed and tamper-evident packaging; except that drugs  
7 packaged in single-unit doses may be accepted and dispensed when the outside  
8 packaging is opened if the single-unit dose packaging is intact.

9 \* \* \*

10 (6) Expired drugs accepted by a charitable pharmacy or a penal institution  
11 pharmacy shall not be redispensed.

12 (7) The charitable pharmacy or a penal institution pharmacy shall comply  
13 with all state and federal laws regarding controlled dangerous substances.

14 (8) No drug dispensed through a charitable pharmacy or a penal institution  
15 pharmacy shall be eligible for reimbursement from the Medicaid Pharmacy Program.

16 \* \* \*

17 D.(1) No person, including a drug manufacturer, health care facility, or  
18 governmental agency who donates prescription drugs to a charitable pharmacy or a  
19 penal institution pharmacy, as well as the charitable pharmacy or the penal institution  
20 pharmacy, any pharmacist who originally dispensed the donated prescription drugs,  
21 any pharmacist dispensing donated prescription drugs, or the board of pharmacy  
22 shall be subject to any professional disciplinary action, criminal prosecution, liability  
23 in tort, or other civil action for injury, death, or loss to person or property related to  
24 the donating, accepting, or dispensing of donated prescription drugs.

25 \* \* \*

26 F. For purposes of this Section "penal institution pharmacy" shall mean any  
27 institutional pharmacy permitted by the board and located within a penal institution

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28 operated by or under the authority of the Department of Public Safety and  
29 Corrections.

## DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument.

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LaBruzzo

HB No. 558

**Abstract:** Permits prescription drug returns to be made to penal institution pharmacies for redispensing to prisoners in that institution.

Present law allows all drugs dispensed on a prescription to a patient to be accepted for return, exchange, or redispensing by a charitable pharmacy in the following instances:

- (1) In a hospital with a permitted hospital pharmacy on site, a drug may be returned to the pharmacy in accordance with good professional practice standards.
- (2) Allows all individuals, including but not limited to drug manufacturers, hospitals, and other health care providers, the ability to donate to a charitable pharmacy.

Proposed law retains present law and further adds that penal institution pharmacies may also accept prescription drug returns for relabeling and redispensing to a prisoner of that institution.

Present law requires that donations to charitable pharmacies meet the following requirements:

- (1) The charitable pharmacy may accept only those drugs in their original sealed and tamper-evident packaging; except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is intact.
- (2) The pharmacist-in-charge of the charitable pharmacy shall determine if the drug is not adulterated or misbranded and is safe to dispense. No product where integrity cannot be assured shall be accepted for redispensing by the pharmacist of the charitable pharmacy.
- (3) The donor shall execute a form stating the donation of the drugs. The pharmacy shall retain that form along with other acquisition records.
- (4) The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to redispensing the medication to another patient.
- (5) The drug name, strength, and expiration date shall remain on the medication package label. The redispensed medication shall be assigned the expiration date stated on the package.

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- (6) Expired drugs accepted by a charitable pharmacy shall not be redispensed.
- (7) The charitable pharmacy shall comply with state and federal laws regarding controlled dangerous substances.
- (8) No drug dispensed through a charitable pharmacy shall be eligible for reimbursement from the Medicaid Pharmacy Program.

Proposed law retains present law but further mandates these requirements apply to a penal institution pharmacy.

Present law authorizes the board of pharmacy to promulgate rules and regulations for purposes of administering present law.

Proposed law retains present law.

Present law exempts pharmaceutical manufacturers from liability for any claim or injury arising from the transfer of any prescription drug to a charitable pharmacy, including limiting liability for failure to transfer or communicate product or consumer information concerning such drug, as well as its expiration date. Present law further exempts all persons, drug manufacturers, health care facilities, or government agencies that donate prescription drugs to a charitable pharmacy from criminal prosecution, tort liability, civil action, death, loss to person, loss to property, or disciplinary action.

Proposed law retains present law and further applies the exemptions to drugs that are donated to a penal institution pharmacy.

Present law exempts the board of pharmacy, the pharmacist at the charitable pharmacy, the pharmacist who originally dispensed the donated prescription drug, and the charitable pharmacy from the above actions.

Proposed law retains present law and further adds penal institution pharmacies to the exemptions.

Proposed law defines "penal institution pharmacy".

(Amends R.S. 37:1226.2(A)(intro. para.) and (2), (B)(intro. para.) and (1), (6), (7), and (8) and (D)(1); Adds R.S. 37:1226.2(F))