

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Chairman Jim Morrison at 1:30 p.m. on February 11, 2004, in Room 526-S of the Capitol.

All members were present except:

Representative Jim Morrison- excused
Representative Judy Showalter- excused
Representative Tom Holland- excused
Representative Joe McLeland - excused

Committee staff present:

Dr. William Wolff, Legislative Research Department
Rena Jefferies, Office of Revisor of Statutes
Gary Deeter, Secretary

Conferees appearing before the committee:

Representative Tom Sloan
Representative Annie Kuether
Gwendolyn Cargnel, Director of Government Relations, American Cancer Society
Ron Hein, Kansas Pharmacy Coalition
Debra Billingsley, Executive Director, Kansas Board of Pharmacy
Peter Obetz, Vice President of Legislation, Kansas Trial Lawyers Association

Others attending:

See Attached List.

The committee minutes for Monday and Tuesday, February 9 and 10, were approved as printed.

Chairing the hearing were Representatives Don Hill and Eber Phelps. Representative Hill opened the hearing on **HB 2538**, which proposed to create a drug repository for the needy through the State Pharmacy Board.

Representative Tom Sloan, as sponsor of the bill, spoke in support, saying the voluntary program was patterned after other state laws that authorize similar service and avoid the waste of valuable and often expensive drugs. (Attachment 1)

Representative Annie Kuether spoke as a proponent, relating that after her husband's death, she had medication that could have helped someone else, but instead the expensive medicines went into a landfill. (Attachment 2)

Gwendolyn Cargnel, Director of Government Relations, American Cancer Society, testified as a proponent, saying that the program will enable unused, unopened, individually packaged prescription drugs to be received from individuals and nursing homes and be re-distributed through pharmacies to low-

CONTINUATION SHEET

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE at 1:30 p.m. on February 11, 2004, in Room 526-S of the Capitol.

income Kansans. (Attachment 3) She said that rather than medications being thrown away, they can be better utilized to help others. She quoted a study asserting that poverty was a critical factor affecting health and longevity, noting that a program such as this bill will lower the financial burden for low-income families who need expensive medications.

Answering questions, she replied that Ohio has fully implemented the concept of the bill, that Nebraska is beginning to implement a similar program, and that Missouri and Oklahoma are considering one. She replied that she knew of no federal statutes that would conflict with this bill. When several members expressed concern over liability, Ms. Cargnel suggested recipients could sign a form releasing the dispensing pharmacy from liability, which would further limit the liability as provided in the bill.

Ron Hein, Legislative Counsel for the Kansas Pharmacy Coalition, an *ad hoc* group comprised of the Kansas Pharmacists Association and the Kansas Federation of Chain Pharmacies, testified as an opponent. (Attachment 4) He listed two issues of concern: public safety and liability. He said the bill removes the chain-of-custody control that insures safe products and thus exposes recipients to the possibility of adulterated or deteriorated drugs and exposes pharmacists to unnecessary liability. He stated that if the program is implemented, many pharmacies will choose not to participate because, although the pharmacist is given immunity from liability, it will not give absolute protection from a lawsuit.

Debra Billingsley, Executive Director, Kansas Board of Pharmacy, stated that the board members had reviewed the bill and have expressed some concerns about provisions in the bill. (Attachment 5) She said the federal law regarding controlled substances will place limitations on what drugs could be recycled. She also noted further limitations on what drugs would be allowed, since the bill stipulates only tamper-proof packaging would be allowed. She said most pharmacists would not participate because most drugs they dispense do not meet the packaging requirements of the bill and noted that the bill duplicates efforts by drug companies, who donate to clinics that specialize in service to low-income clients, such as the Marian Clinic in Topeka. Further, she said that the bill would not allow the Pharmacy Board to discipline a pharmacist for incompetence or negligence, only for intentional bad-faith re-dispensing of drugs. She said that implementing the bill would have some fiscal impact, since the Pharmacy Board would need to develop ID cards, an inspection program, and create a legal form for immunity.

Peter Obetz, Vice President of Legislation, Kansas Trial Lawyers Association, said he appreciated the intent of the bill, but was concerned about unclear wording. (Attachment 6) He said the guidelines for determining the expiration date of a drug were not clear. He stated that blanket immunity for all participants in the chain of custody set a dangerous precedent, and he noted that the term "bad faith" was not defined. He provided a balloon amendment to rectify the wording ambiguities.

The Chair closed the hearing on **HB 2538**.

Staff Bill Wolff briefed the Committee on two bills:

CONTINUATION SHEET

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE at 1:30 p.m. on February 11, 2004, in Room 526-S of the Capitol.

Regarding **HB 2634**, testing for West Nile virus in humans, he said the bill requires the Kansas Department of Health and Environment (KDHE) to run a West Nile test on a person whenever a person requests such a test and to report back the results of the test.

Regarding **HB 2716**, he stated that the bill changes the requirements for care home administrators. Noting that the first part of the bill's title is inaccurate and not applicable, he said the bill adds a definition for a preceptor and sets forth qualifications for the position: the person must hold a current license as adult care home administrator, have at least 3 years of experience, and have completed a course of training. After noting that the term "practicum is unclear, he said Section 2 states that it is the duty of the Board of Adult Care Home Administrators to impose and enforce standards, further stating that the bill increases the fee limitation from \$200 to \$400.

The Vice-Chair reminded members that at the next meeting the Attorney General's Office would brief the Committee on the Open Meetings Act. She then adjourned the meeting at 2:22 p.m. The next meeting is scheduled for Thursday, February 12, 2004.

**Testimony on HB 2538 by Representative Tom Sloan
Creation of a Drug Repository System**

Mr. Chairman, Members of the Committee:

HB 2538 is based on a simple concept—that when persons no longer need prescription medications, they should be able to donate the unopened package for use by other persons who might otherwise be unable to afford the medication. Similar laws have been passed in a handful of states and this bill is modeled on an Ohio statute.

The program created by **HB 2538** is voluntary—patients or their survivors may choose to donate the medications, or they may choose not to do so.

Hospitals, pharmacies, and non-profit clinics may choose to receive and dispense the donated medications, or they may choose not to participate. Please note, that all donated medications may subsequently only be dispensed through physician written prescriptions..

Why is this bill desired? When a person's medical condition changes, too often unused medications are simply tossed into the trash can. The drugs remain viable, having already been paid for, and can help others without health insurance.

As an aside, Gail and I make periodic, anonymous cash donations to our local pharmacy to help pay for needed medication for elderly, less affluent customers. If the pharmacist also has the option of dispensing unopened, donated medications, customers benefit because the pharmacist's "donations" and gifts like Gail's and mine go farther. The program proposed in **HB 2538** will be in addition to donations made by pharmaceutical companies.

HB 2538 requires the Board of Pharmacy to establish the drug repository program and is, accordingly, provided rules and regulation authority.

Will many patients, or their survivors, participate? I do not know, but I believe that the program will succeed as the public becomes aware of the opportunity. .

Mr. Chairman, I suspect that other conferees will have proposed amendments to further clarify how a repository can best be established and operated. My goal in introducing **HB 2538** was, and remains, to avoid the waste of often very expensive medications when they can help alleviate pain in other patients. I support all proposed amendments that help us achieve that goal.

Thank you for you attention and consideration. I will be pleased to respond to questions.

Attachment 1
HHS 2-11-04

From: <Kuet@aol.com>
To: <health@house.state.ks.us>
Date: Tue, Feb 10, 2004 10:58 AM
Subject: HB 2538

Dear Chairman Morrison and Committee Members:

Thank you for allowing me to appear before you today in support of HB 2538.

Simply, this legislation establishes a drug repository program to account and dispense donated prescription drugs.

My support of this proposal comes from a very personal nature. In January of 1998, my husband, John, died from lung cancer. Even though his disease took him quickly, we accumulated vast amounts of various drugs, prescribed to help John.

After his death, it was overwhelming to open up the bathroom closet door and to see the shelves filled with prescription drugs that now, I had no use for. My thought was that I could simply give the medicine back...and that was not the case. And not only was the sheer amount too much to think about dealing with, knowing just how much money had been spent...some of his shots cost over \$1,000.00 a piece...now all of this medicine was going to be thrown out! I only wanted somebody else to be able to use it. This bill allows that to happen.

A year after my husband died, one of his best friends died. Having gone through the experience, I went to the house and cleared out all medication, oxygen bottles, etc. These are things those left behind, don't want to see or deal with after the death of a loved one.

This bill will help those in need, who can't necessarily get the medication they need due to the sheer cost of rising health care costs. It will help survivors to move on and perhaps give some peace of mind that others have benefited from medication, despite our loss. I know I would have.

Please support HB 2538 favorably.

Thank you.

Annie Kuether
55th District

Attachment 2
HHS 2-11-04

February 11, 2004

House Committee on Health and Welfare
SB 2538

Chairman and Members of the Committee:

My name is Gwendolyn Cargnel, Director of Government Relations for the American Cancer Society. I represent over 270,000 volunteers and supporters in Kansas, and on their behalf, I would like to thank you for the opportunity to speak in support House Bill 2538.

House Bill 2538 will establish a Drug Repository Program for the State of Kansas. This program will accept unused, unopened, individually packaged prescription drugs from nursing homes and individuals to be redistributed through pharmacies, that have volunteered to participate, to low-income Kansans.

Often when a person passes away their loved ones are forced to throw away hundreds of dollars worth of medication that could save the life of a fellow Kansan. Many times patients with life threatening illnesses cannot afford the medications they need. The Drug Repository Program could provide low-income and uninsured Kansans access to life-saving medications.

This year almost 13,000 Kansans will be diagnosed with cancer and more than 5,300 will die. According to a 2003 report by the Institute of Medicine, poverty is the most critical factor affecting health and longevity. This program will provide a mechanism to help eliminate the disparity in the cancer burden for the socioeconomically disadvantaged population.

This is a population that often goes without proper treatment and proper medication. I urge this Committee to recommend HB 2538 for passage to the House.

Attachment 3
HHS 2-11-04

HEIN LAW FIRM, CHARTERED

5845 SW 29th Street, Topeka, KS 66614-2462

Phone: (785) 273-1441

Fax: (785) 273-9243

Ronald R. Hein

Attorney-at-Law

Email: rhein@heinlaw.com

Testimony re: HB 2538
House Health and Human Services Committee
Presented by Ronald R. Hein
on behalf of
Kansas Pharmacy Coalition
February 11, 2004

Mr. Chairman, Members of the Committee:

My name is Ron Hein, and I am legislative counsel for the Kansas Pharmacy Coalition (KPC). The Kansas Pharmacy Coalition is an ad hoc coalition comprised of the Kansas Pharmacists Association and the Kansas Federation of Chain Pharmacies.

HB2538 provides for a voluntary drug repository system which, on its face, would appear to be an excellent means to facilitate donated drugs being made available to patients who meet eligibility guidelines to receive drugs which they may not otherwise be able to afford. In short, we believe the intentions of this bill, and of the sponsor, are highly commendable.

In numerous ways, the goals of this legislation are currently being achieved and can be achieved through other mechanisms. Charitable aid for people needing medical assistance is available through countless public and private programs. For starters, our organization will always stand ready to help explore new ways to create better incentives for improving and expanding care.

However, the method suggested in HB2538 is not safe and it would conflict with laws that provide a good system today for ensuring drug safety. In light of that, KPC would oppose passage of this legislation.

The key in programs such as this is having a safe chain of custody. Both federal and state laws set boundaries on how pharmacies may package and distribute medications. Limited options for how any pharmacy may legally re-package medications are carefully defined so that the risk of drug contamination is best avoided.

Even if pharmacies were given broader statutory latitude in re-dispensing drugs under certain conditions, every pharmacy would still have a major liability question to consider. There are numerous unknown, unintentional, and unknowable opportunities for mistakes or illicit tampering injected into the process as the chain of custody gets extended. The

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House Health and Human Services
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liability for such uncontrolled factors could easily fall on the re-dispensing pharmacy, despite efforts to provide immunity under the legislation.

Typically, a pharmacy would, understandably, be concerned about the possibility of adulteration or deterioration of product in cases where the drugs to be re-distributed (1) have not come directly from their regulated channels, (2) were initially dispensed by a different pharmacy, or (3) have been handled by unknown entities.

We want to reiterate that the intent of this bill is admirable, and we appreciate the sponsor thinking outside the box to try to find a way to bring unused medications and people who need medications together. However, any such program must satisfy the most important concern, which is public safety. This is not just a liability issue for pharmacies, this is an issue of safety for the patients and for society. Even if pharmacies were guaranteed immunity from legal liability, we would not want to jeopardize any patient's health by supplying medications that may not be safe.

Thank you very much for permitting me to testify, and I will be happy to yield to questions.

Testimony re: HB 2538
House Health and Human Services Committee
Presented by Debra L. Billingsley
February 11, 2004

Mr. Chairman, Members of the Committee:

My name is Debra Billingsley, and I am the Executive Director of the Kansas Board of Pharmacy. The Board of Pharmacy consists of six members, five of who are licensed pharmacists, and one who is a representative of the general public. The Board's mission is that all persons and entities conducting business relating to the practice of pharmacy in this state be properly licensed and registered so as to protect the public's health, safety, and welfare and to promote the education and understanding of pharmacy related services.

HB 2538 establishes a drug repository program that would accept donations of prescription only drugs and dispense them to Kansas residents who meet certain eligibility requirements. The drugs may be donated by any person, drug manufacturer, or health care facility to a participating pharmacy, hospital or nonprofit clinic.

This bill has been authored with the best intentions and the Board's position is that any discourse that plans on providing safe and affordable health care to Kansans is worthy of discussion.

The Board supports the intentions behind the bill but would like to address some areas of concern.

The term prescription drug is defined in the Pharmacy Act and in federal law as any drug dispensed pursuant to a written or oral prescription or order of a practitioner. This would include controlled substances. Federal law, specifically 21 CFR 290.5, prohibits the transfer of a controlled substance to any person other than the patient for whom it was prescribed. Therefore, the language in the bill as written would violate federal law.

The Kansas Pharmacy Act also has a law that provides that prescription drugs that have been dispensed to the final consumer shall not be resold, re-dispensed, or re-distributed. The only exception is unit-dose systems with one medication where the drug hasn't reached the patient.

The reason that the federal law and state law prohibit members of the general public from returning their personal drugs, for distribution to others, are for safety reasons. This prevents any problems with tampering or storage. Many drugs are to be maintained at certain temperatures so these laws ensure that patients are receiving a safe and an effective product. We cannot ensure that the product is safe or effective when it reaches the hands of the consumer and then is put back into general stock for re-distribution.

Attachment 5
HHS 2-11-04

Kansas's pharmacy law does permit patients who are receiving unit-dose systems the ability to return the medication for credit if it has not reached the patient. (See K.A.R. 68-12-2) This is particularly useful in the nursing home setting. If the drug does not reach the patient and his prescription changes or if the patient passes away the family may return the drug for credit.

This bill may duplicate some other efforts that are currently being made by drug companies. Manufacturers are currently donating pharmaceuticals to doctor's offices and to charitable organizations. They generally provide samples at no cost to the organization and they may only be given to the patient for free. Charitable clinics such as the Marian Clinic in Topeka are provided such samples and they give these to patients every day. There is also a Health Access program available in some Kansas counties. In this program a card is given to person that meets eligibility for assistance. The patient pays approximately \$4 for each prescription up to a maximum of \$740 a year. The Marian Clinic in Topeka is currently using this program. The Federal Government has the 340B Drug Discount Program that assists County Health Agencies and Charitable Organizations in providing low cost pharmaceuticals to eligible patients. I know that the Shawnee County Health Department has been exploring the use of this program although it is not currently in effect. Many of the chain pharmacies also have programs that assist low-income families with payment for pharmaceuticals if the patient applies for assistance. There is a program whereby physicians can apply for particular patients to receive complimentary drugs directly from the manufacturer. We would want to explore whether this bill will duplicate any of the efforts already available.

The bill has an expiration date of medication that can be used in this program of up to six months. Drugs in unit dose packaging have a one-year expiration date. The short date may eliminate some of the drugs that would otherwise be available for use.

The Board also wanted the Committee to reconsider any provision that would totally absolve persons donating from responsibility and liability. There is no accountability in this bill unless bad faith can be shown. Bad faith infers that an intentional act is done in order to achieve something. This would mean that if a licensee were professionally incompetent, negligent, or physically or mentally handicapped to such a degree that he would be unfit to practice, there might possibly be no legal liability. The Board is concerned that safety would be compromised absent an intentional act. We should apply the same safeguards for indigent patients as we apply toward any other patient.

The Board would request that the Committee review this bill more fully to make sure that the integrity issues are resolved. The Board of Pharmacy would be able to assist in any discussions or provide specific information if needed.

Thank you very much and I will be happy to answer any questions that you might have.

To: House Health and Human Services Committee

From: Peter Obetz, Vice President of Legislation
Kansas Trial Lawyers Association

Re: 2004 HB 2538

Date: February 11, 2004

Chairman Jim Morrison and members of the House Health and Human Services Committee. Thank you for the opportunity to submit comments in opposition to HB 2538. My name is Peter Obetz and I currently serve as Vice President of Legislation for the Kansas Trial Lawyers Association, KTLA. KTLA is a statewide, nonprofit organization of lawyers who represent consumers and advocate for the safety of families and the preservation of the civil justice system.

KTLA supports the purpose of HB 2538 as related to allowing for the donation of unused prescription drugs so that the unused prescription drugs can be used by others instead of being discarded.

However, there are three basic areas of concern: (1) clarification concerning expiration dates; (2) immunity; and (3) definition of "bad faith".

First, we submit that a clarification of Section 1 (b) should be made so that it is clear that prescription drugs can be donated only before their expiration date. The language in HB 2538 appears to allow donation of prescription drugs either earlier than six months before the expiration date, or later than six months after the expiration date. We have attached a balloon with our proposed amendments which we request you approve.

Second, Sections 3(a) and (b) provide immunity for essentially everyone in the chain. HB 2538 expressly gives a pharmaceutical manufacturer immunity for criminal prosecution, tort liability or other civil action for injury or death. On behalf of Kansas consumers, KTLA objects to blanket immunity for a pharmaceutical manufacturer who sells or donates prescription drugs which kill or injure Kansas consumers. Immunity for a pharmaceutical manufacturer - regardless of whether it sells or donates the prescription drug which kills or injures Kansas consumers -- violates public policy. This immunity provision is a significant departure from existing public policy and tort law in the State of Kansas and therefore is opposed by the Kansas Trial Lawyers Association.

Attachment 6
HHS 2-11-04

KTLA does not object to immunity for the state board of pharmacy, the secretary of health and environment, any private individual or corporation other than a pharmaceutical manufacturer, or a governmental entity that donates prescription drugs to the repository program. The objection is limited to immunity being given to pharmaceutical manufacturers in Sections 3 (a) and (b).

Third, HB 2538 refers to donating, accepting or dispensing drugs in "bad faith". However, "bad faith" is not defined. We submit that a definition of "bad faith" should be included in Section 1 and should include altering, changing, modifying, reformulating, tampering and misbranding.

Thank you for the opportunity to express our concerns about HB 2538.

HOUSE BILL No. 2538

By Representative Sloan

1-21

AN ACT establishing under the state board of pharmacy a drug repository program to accept and dispense donated prescription drugs.

Be it enacted by the Legislature of the State of Kansas:

Section 1. (a) As used in this act:

(1) "Health care facility" means any of the following:

(A) A hospital;

(B) a hospice care program or other institution that specializes in comfort care of patients in a terminal condition or in a permanently unconscious state;

(C) a nursing facility;

(D) a home health agency;

(E) an intermediate care facility for the mentally retarded;

(F) a mental health center;

(G) a mental health clinic.

(2) "Health care professional" means any of the following who provide medical, dental or other health-related diagnosis, care or treatment:

(A) Persons licensed to practice medicine and surgery or podiatric medicine and surgery;

(B) licensed professional and licensed practical nurses;

(C) licensed physician assistants;

(D) licensed dentists and dental hygienists;

(E) licensed optometrists;

(F) licensed pharmacists.

(3) "Hospital" has the same meaning as in K.S.A. 65-425 and amendments thereto.

(4) "Nonprofit clinic" means a charitable nonprofit corporation organized as a nonprofit corporation under the laws of this state or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons. "Nonprofit clinic" does not include a hospital or a facility that is operated for profit.

(5) "Prescription-only drug" has the same meaning as in K.S.A. 65-1626 and amendments thereto.

(b) The state board of pharmacy shall establish a drug repository pro-

Section 1 (a)(6) "Bad faith", as used in this section, includes, but is not limited to, altering, changing, modifying, reformulating, tampering, or misbranding any prescription-only drug.

1 gram to accept and dispense prescription-only drugs donated for the pur-
 2 pose of being dispensed to individuals who are residents of this state and
 3 meet eligibility standards established in rules and regulations adopted by
 4 the board under section 4 and amendments thereto. Only drugs in their
 5 original sealed and tamper-evident unit dose packaging may be accepted
 6 and dispensed. The packaging must be unopened, except that drugs pack-
 7 aged in single unit doses may be accepted and dispensed when the outside
 8 packaging is opened if the single unit dose packaging is undisturbed.
 9 ~~Drugs donated by individuals bearing an expiration date that is less than~~
 10 ~~six months from the date the drug is donated shall not be accepted or~~
 11 ~~dispensed.~~ A drug shall not be accepted or dispensed if there is reason
 12 to believe that it is adulterated. Subject to the limitation specified in this
 13 act, unused drugs dispensed for purposes of the medicaid program may
 14 be accepted and dispensed under the drug repository program.

Drugs may be donated
 at any time prior to six
 months before the expiration
 date. In any event, no drug
 may be dispensed after the
 expiration date.

15 Sec. 2. (a) Any person, including a drug manufacturer or any health
 16 care facility, may donate prescription drugs to the drug repository pro-
 17 gram. The drugs must be donated at a pharmacy, hospital or nonprofit
 18 clinic that elects to participate in the drug repository program and meets
 19 criteria for participation in the program established by rules and regula-
 20 tions adopted by the state board of pharmacy. Participation in the pro-
 21 gram by pharmacies, hospitals and nonprofit clinics is voluntary. Nothing
 22 in this act or any other statutes of this state requires a pharmacy, hospital
 23 or nonprofit clinic to participate in the program.

24 (b) A pharmacy, hospital or nonprofit clinic eligible to participate in
 25 the program shall dispense drugs donated under this section to individuals
 26 who are residents of this state and meet the eligibility standards estab-
 27 lished by rules and regulations adopted by the board or to other govern-
 28 ment entities and nonprofit private entities to be dispensed to individuals
 29 who meet the eligibility standards. A drug may be dispensed only pur-
 30 suant to a prescription issued by a person authorized to prescribe drugs.
 31 A pharmacy, hospital or nonprofit clinic that accepts donated drugs shall
 32 comply with all applicable federal laws and laws of this state dealing with
 33 storage and distribution of dangerous drugs and shall inspect all drugs
 34 prior to dispensing them to determine that they are not adulterated. The
 35 pharmacy, hospital or nonprofit clinic may charge individuals receiving
 36 donated drugs a handling fee established in accordance with rules and
 37 regulations adopted by the board. Drugs donated to the repository may
 38 not be resold.

any private individual or
 corporation other than a
 pharmaceutical manufacturer,

39 Sec. 3. (a) The state board of pharmacy, the secretary of health and
 40 environment, ~~any person, including a drug manufacturer~~ or government
 41 entity, that donates drugs to the repository program; any pharmacy, hos-
 42 pital, nonprofit clinic or health care professional that accepts or dispenses
 43 drugs under the program; and any pharmacy, hospital or nonprofit clinic

1 that employs a health care professional who accepts or dispenses drugs
2 under the program, in the absence of bad faith, shall not be subject to
3 any of the following for matters related to donating, accepting or dis-
4 pensing drugs under the program: criminal prosecution, liability in tort
5 or other civil action for injury, death or loss to person or property or
6 professional disciplinary action.

7 ~~(b) A drug manufacturer, in the absence of bad faith, shall not be~~
8 ~~subject to criminal prosecution or liability in tort or other civil action for~~
9 ~~injury, death or loss to person or property for matters related to the~~
10 ~~donation, acceptance or dispensing of a drug manufactured by the drug~~
11 ~~manufacturer that is donated by any person under the program, including~~
12 ~~but not limited to, liability for failure to transfer or communicate product~~
13 ~~or consumer information or the expiration date of the donated drug.~~

14 Sec. 4. The state board of pharmacy shall adopt rules and regulations
15 governing the drug repository program that establish all of the following:

16 (a) Eligibility criteria for pharmacies, hospitals and nonprofit clinics
17 to receive and dispense donated drugs under the program;

18 (b) standards and procedures for accepting, safely storing and dis-
19 pensing donated drugs;

20 (c) standards and procedures for inspecting donated drugs to deter-
21 mine that the original unit dose packaging is sealed and tamper-evident
22 and that the drugs are unadulterated, safe and suitable for dispensing;

23 (d) eligibility standards based on economic need for individuals to
24 receive drugs;

25 (e) a means, such as an identification card, by which an individual
26 who is eligible to receive donated drugs may demonstrate eligibility to
27 the pharmacy, hospital or nonprofit clinic dispensing the drugs;

28 (f) a form that an individual receiving a drug from the repository must
29 sign before receiving the drug to confirm that the individual understands
30 the immunity provisions of the program;

31 (g) a formula to determine the amount of a handling fee that phar-
32 macies, hospitals and nonprofit clinics may charge to drug recipients to
33 cover restocking and dispensing costs;

34 (h) in addition, for drugs donated to the repository by individuals:

35 (1) A list of drugs, arranged either by category or by individual drug,
36 that the repository will accept from individuals;

37 (2) a list of drugs, arranged either by category or by individual drug,
38 that the repository will not accept from individuals, which list shall include
39 a statement as to why the drug is ineligible for donation; and

40 (3) a form each donor must sign stating that the donor is the owner
41 of the drugs and intends to voluntarily donate them to the repository;

42 (i) in addition, for drugs donated to the repository by health care
43 facilities:

1 (1) A list of drugs, arranged either by category or by individual drug,
2 that the repository will accept from health care facilities;

3 (2) a list of drugs, arranged either by category or by individual drug,
4 that the repository will not accept from health care facilities, which list
5 shall include a statement as to why the drug is ineligible for donation;

6 (j) any other standards, procedures or matters the board considers
7 appropriate to carry out the provisions of this act.

8 Sec. 5. This act shall take effect and be in force from and after its
9 publication in the statute book.

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