ACT 190 H.B. NO. 2005

A Bill for an Act Relating to Prescription Drugs.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. The legislature finds that costly prescription drugs are sometimes wasted because once they have been dispensed, they may not be used by anyone other than the individual for whom the medication was prescribed. Unused drugs could be provided to the needy and other individuals who lack the means to obtain prescription drugs.

The purpose of this Act is to:

(1) Establish a mechanism to encourage donations to repositories that will provide prescription drugs to the needy and other state residents who lack the means to obtain the amounts or types of prescription drugs prescribed for them by a health care provider;
(2) Prevent the waste of prescription drugs by allowing these drugs to be reused by institutional facilities, upon meeting certain conditions; and
(3) Allow donated drugs not used or accepted by repositories in the state for use outside of the state.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER
RETURN-FOR-CREDIT-AND-REUSE OF PRESCRIPTION DRUGS

§ **-1 Definitions.** For the purposes of this chapter:

"Institutional facility" means an organization or facility whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, and that uses the services of an on-site pharmacy, an off-site pharmacy, or a pharmacist contractor at which medication storage is managed by personnel of the facility. "Institutional facility" includes but is not limited to a:

(1) Hospital;
(2) Convalescent home;
(3) Skilled nursing facility;
(4) Intermediate care facility;
(5) Extended care facility;
(6) Rehabilitation center;
(7) Health maintenance organization clinic;
(8) Psychiatric center;
(9) Mental retardation center;
(10) Penal institution;
(11) Hospice facility;

(12) Supervised living group; or
(13) Prescribing practitioner's office.

"Pharmacy" means a place of business operating as a pharmacy as permitted under chapter 461.

"Return-for-credit-and-reuse" as it pertains to prescription drugs means the process by which prescription drugs dispensed by the dispensing pharmacy of an institutional facility are safely returned to that pharmacy and redispensed for purposes of patient or resident care, or both, which process includes the appropriate crediting of the cost of returned drugs to the payer, less handling fees to providers where applicable, recordkeeping, and the return of the drugs to pharmacy stock for redispensing.

§ **-2 Return-for-credit-and-reuse of prescription drugs.** (a) Previously dispensed prescription drugs may be returned to the dispensing pharmacy for credit to the payer and subsequent reuse as provided by this chapter; provided that:

(1) The prescription drug:
  (A) Is in its original dispensed, unopened, untampered multiple dose container or unopened, untampered single user unit;
  (B) Has remained at all times under the control or direction of a person in the institutional facility or the pharmacy trained and knowledgeable in the storage of drugs, including periods in transit by any carrier for hire or person or entity hired solely to transport prescription drugs;
  (C) Is not adulterated or misbranded;
  (D) Has been stored under conditions meeting United States Pharmacopoeia standards;
  (E) Is returned and redispensed or redistributed before the expiration date or use by date on the multiple dose container or single user unit;
  (F) Has not been in the possession of an individual member of the public;
  (G) Is not included within the classification of controlled substances, as defined in applicable federal and state laws; and
  (H) Is first offered for donation to a drug repository entity pursuant to chapter 328C for local distribution for needy persons;
(2) Appropriate credits and handling fees are applied;
(3) Appropriate recordkeeping provides for documentation of receipt, transfer, and credit;
(4) The prescription drugs are returned only to the original dispensing pharmacy; and
(5) Prescription drugs from individual members of the public are not accepted for reuse.

(b) Prescription drugs are not appropriate for return-for-credit-and-reuse and shall not be returned for credit under this chapter under conditions which include but are not limited to the following:

(1) Product valuation is less than the handling fee;
(2) Market demand makes reuse implausible by the expiration date or use by date;
(3) The product prescription number or patient identifier is not discernable, therefore credit to the payer is not possible; or
(4) The prescription drugs are in containers that do not have a tamperproof seal demonstrating that it has never before been opened.

(c) Prescription drugs that are not returnable for credit may be donated as provided in chapter 328C.

§ -3 **Credit and reimbursement for handling returned drugs.** (a) Prescription drugs that have been refused on delivery and are returned to the dispensing pharmacy shall be credited to the payer in full and shall not be subject to a handling fee.

(b) If prescription drugs returned to the dispensing pharmacy have been previously billed to the payer, the payer shall be credited for the quantity of drugs returned, not including the original dispensing fee, and less any handling fee. An appropriate handling fee, not to exceed the institutional facility's actual cost of processing returned prescription drugs and the receiving pharmacy's actual cost of receiving and processing returned prescription drugs, shall be established by the department of human services. The handling fee shall not reduce the credit amount below zero. Dispensed and billed drugs with a valuation below the handling fee shall not be returnable for credit under this chapter.

(c) The pharmacy shall reimburse the institutional facility for the proper storage and recordkeeping of returned drugs from the handling fee as determined in subsection (b), if any.

(d) Returned prescription drugs may be sold by prescription subject to the provisions of this chapter.

§ -4 **Recordkeeping.** (a) The institutional facility shall keep records of all previously dispensed prescription drugs returned to the dispensing pharmacy. Records shall be retained for five years and shall include at least the following:

(1) The name and address of the institutional facility;
(2) The prescription number or other patient or payer identifier;
(3) The name and strength of the drug;
(4) The name of the manufacturer or the national drug code;
(5) The quantity of the drug;
(6) The expiration date or use by date;
(7) The date the drug was sent to the pharmacy, repository entity, or any other agent for final disposition;
(8) The name of the pharmacy, repository entity, or any other agent that received or is to receive the drug for final disposition and a description of the disposition, such as returned-for-credit-and-reuse, donated, disposed, or destroyed;
(9) The initials of the person making the entry; and
(10) Certification of the reason for the return of the prescription drug by a prescribing practitioner.

(b) Records of drugs to be returned-for-credit-and-reuse shall be copied by the institutional facility and used as a manifest for products sent to the recipient pharmacy. The manifest and products shall be reviewed by the pharmacy prior to accepting or receiving all products to ensure that products are returnable for credit. Any discrepancies shall be noted and corrected by the recipient pharmacy. The accepted manifest noting any corrections shall be retained for five years by both the institutional facility and the pharmacy. Records may be electronically composed, stored, and maintained in a form retrievable and printable for audit purposes. Returned product manifests shall be reconcilable with credits to payers.

(c) All institutional facility and pharmacy records required by this chapter shall be subject to audit by agents of the director of human services or director of health.

§ -5 **Pharmacy certification requirements.** (a) A high managerial agent acting on behalf of the pharmacy shall cause to be filed, with the designated state agency responsible for administering the medicaid program, a certified transaction

account detailing every transaction under this chapter. The certified transaction account shall include the following information relative to each drug returned:

(1) If the transaction involved medicaid:
   (A) The medicaid provider number of the pharmacy;
   (B) The medicaid provider number of the institutional facility;
   (C) The name and beneficiary identification number of the medicaid beneficiary to whom the returned drug was originally prescribed;
   (D) The name and provider number of the physician who originally prescribed the drug;
   (E) The NDC number appearing on the original prescription;
   (F) The lot number, if available;
   (G) The medicaid claim number of the original prescription;
   (H) The medicaid transaction number of the credit for the returned drug; and
   (I) The reason for the return of the drug;
(2) If the transaction involves the federal medicare program:
   (A) A copy of the 204-claim form, or its then existing equivalent, detailing the original transaction;
   (B) Documentation of the corresponding credit to the federal medicare program; and
   (C) Any other information required by the federal administrators of the medicare program; and
(3) If the transaction involves a private pay patient in an institutional facility, a certification that the payer was properly credited.

(b) The same agent who filed the certification under this section shall concurrently certify that no drugs, other than those detailed in the transaction account, were returned to the pharmacy during that quarter. The agent shall further certify that all drugs accepted for return were either safe for resale, or were disposed of in accordance with the laws of this state and federal laws governing disposal of medication.

(c) The quarterly certifications shall be filed no later than April 1, July 1, October 1, and December 31 of each calendar year.

(d) For purposes of this section, "high managerial agent" has the same meaning as provided in section 702-229(3).

§ -6 **Rules.** The department of human services and the department of health shall each create and adopt such rules as may be necessary to carry out the purposes and enforce the provisions of this chapter.

§ -7 **Exception to liability.** No pharmaceutical manufacturer shall be liable for any claim or injury arising from the return and reuse of any prescription drug pursuant to this chapter, including but not limited to liability for failure to transfer or communicate product or consumer information or expiration date information regarding the transferred drug."

SECTION 3. Chapter 328C, Hawaii Revised Statutes, is amended by adding two new sections to be appropriately designated and to read as follows:

"**§328C- Donated drugs repository.** (a) Prescription drugs that meet the requirements of section 461- , but are otherwise not appropriate for return-for-credit-and-reuse as defined in section -2, may be donated to repository entities. Prescription drugs from individual members of the public shall not be accepted for donation.

(b) Donations to repository entities shall be made without credit to the original payer for the cost of the drugs.

(c) Prescription drugs donated to a repository shall have the patient's name removed or redacted from the product, including the label.

(d) Drugs donated under this section that are not used or accepted by a repository in the state of Hawaii may be distributed to repositories for use outside of the state.

§328C- Recordkeeping. (a) All previously dispensed prescription drugs donated to repository entities shall be recorded by the institutional facility. Records shall be retained by the institutional facility for five years and shall include the following information:

(1) The name and address of the donating institutional facility;
(2) The name and strength of the drug;
(3) The name of the manufacturer or the national drug code;
(4) The quantity of the drug;
(5) The expiration or use by date of the drug;
(6) The date the drug was sent to the repository entity or any other agent for final disposition;
(7) The name of the repository entity, or any other agent that received or is to receive the drug for final disposition and a description of the disposition, such as donated, disposed, or destroyed; and
(8) The initials of the person making the entry.

(b) The institutional facility's records of drugs subject to donation to repository entities shall be copied and used as a manifest for the products sent to the recipient repository entity.

(c) All institutional facility and repository records shall be subject to audit by agents of the director of human services or director of health."

SECTION 4. Section 328C-1, Hawaii Revised Statutes, is amended by adding four new definitions to be appropriately inserted and to read as follows:

"<u>"Pharmaceutical company" means any company that manufactures pharmaceuticals and health care supplies.</u>

<u>"Pharmacy" has the same meaning as provided in section 461-1.</u>

<u>"Prescription drug" means:</u>

<u>(1) Any drug required by federal or state statutes, regulations, or rules to be dispensed only upon prescription, including finished dosage forms and active ingredients subject to section 328-16 or section 503(b) of the Federal Food, Drug, and Cosmetic Act; or</u>
<u>(2) Any drug product compounded or prepared pursuant to the order of a practitioner, as defined in section 461-1.</u>

<u>"Repository" means:</u>

<u>(1) A charitable, religious, or nonprofit organization as defined in section 328C-1, licensed as a wholesale prescription drug distributor pursuant to section 461-8.6; or</u>
<u>(2) A foreign medical aid mission group that distributes pharmaceuticals and healthcare supplies to needy persons abroad.</u>"

SECTION 5. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§461- Return of prescription drugs.** Prescription drugs previously dispensed or distributed by a pharmacy for administration to patients in an institu-

tional facility by personnel of the institutional facility may be returned to and redispensed or redistributed by the pharmacist if the prescription drug:

(1) Is in:
  (A) Its original dispensed, unopened, untampered multiple dose container or unopened, untampered single user unit; or
  (B) An in-use multiple dose container subject to appropriate safeguards as defined in rules for public health or operational considerations;
(2) Has remained at all times under the control or direction of a person in the institutional facility or the pharmacy trained and knowledgeable in the storage of drugs, including periods in transit by any carrier for hire or person or entity hired solely to transport prescription drugs;
(3) Is not adulterated or misbranded;
(4) Has been stored under conditions meeting United States Pharmacopoeia standards;
(5) Is returned and redispensed or redistributed before the expiration date or use by date on the multiple dose container or single user unit;
(6) Has not been in the possession of an individual member of the public; and
(7) Is not included within the classification of controlled substances, as defined in applicable federal and state laws.

Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by law with respect to drugs included or that may be included within the classification of controlled substances, as defined in applicable federal and state laws. Previously billed returned drugs shall be subject to crediting to the payer pursuant to chapter ."

SECTION 6. Section 461-1, Hawaii Revised Statutes, is amended by adding eight new definitions to be appropriately inserted and to read as follows:

"'"Institutional facility" means an organization or facility whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, and that uses the services of an on-site pharmacy, an off-site pharmacy, or a pharmacist contractor at which medication storage is managed by personnel of the facility. "Institutional facility" includes but is not limited to a:

(1) Hospital;
(2) Convalescent home;
(3) Skilled nursing facility;
(4) Intermediate care facility;
(5) Extended care facility;
(6) Rehabilitation center;
(7) Health maintenance organization clinic;
(8) Psychiatric center;
(9) Mental retardation center;
(10) Penal institution;
(11) Hospice facility;
(12) Supervised living group; or
(13) Prescribing practitioner's office.

"Multiple dose container" means a multiple unit container for articles intended for parenteral administration only.

"Multiple unit container" means a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

"Single dose container" means a single unit container for articles intended for parenteral administration only. A single dose container is labeled as such. Examples of single dose containers include pre-filled syringes, cartridges, fusion sealed containers, and closure-sealed containers when so labeled.

"Single unit container" is one that is designed to hold a quantity of drug product intended for administration as a single dose or a single finished device intended for use promptly after the container is opened. Preferably, the immediate container and the outer container or protective packaging shall be so designed as to show evidence of any tampering with the contents. Each single unit container shall be labeled to indicate the identity, quantity and strength, name of the manufacturer, lot number, and expiration date of the article.

"Single user unit" means any single unit container, single dose container, unit dose container, unit of use container, or multiple unit container provided for the exclusive use by a single patient.

"Unit dose container" means a single unit container for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit of use container" means one that contains a specific quantity of a drug product and that is intended to be dispensed as such without further modification except for the addition of appropriate labeling. A unit of use container is labeled as such."

SECTION 7. Section 328C-2, Hawaii Revised Statutes, is amended to read as follows:

"**§328C-2 Exceptions to liability.** (a) A charitable, religious, or nonprofit organization which in good faith receives pharmaceuticals or health care supplies, apparently fit for human consumption or external use, and distributes them to needy persons at no charge, shall not be liable for any civil damages or criminal penalties resulting from the use of the pharmaceuticals or health care supplies donated to needy persons unless an injury or illness results to those needy persons as a result of that organization's gross negligence or wanton acts or omissions.

(b) Any pharmacy, wholesale prescription drug distributor, pharmaceutical company, institutional facility, or practitioner that in good faith provides pharmaceuticals, including previously dispensed prescription drugs, and health care supplies to needy persons without remuneration or expectation of remuneration, shall be exempt from civil liability for injuries and damages resulting from their acts or omissions in providing pharmaceuticals and health care supplies, except for gross negligence, or wanton acts or omissions on the part of the pharmacy, wholesale prescription drug distributor, pharmaceutical company, institutional facility, or practitioner.

(c) Any donated, previously dispensed, prescription drug:

(1) Shall be in its dispensed, unopened, tamper-evident single user unit;

(2) Shall have remained at all times in the control of a person trained and knowledgeable in the storage and administration of drugs in institutional facilities;

(3) Shall not have been adulterated, misbranded, or stored under conditions contrary to standards established by the United States Pharmacopoeia or the product manufacturer; [~~and~~]

(4) Shall be used before the expiration date on the unit[~~.~~];

(5) Shall not have been in the possession of an individual member of the public; and

(6) Shall not be included within the classification of controlled substances, as defined in applicable federal and state laws.

(d) This section shall not relieve any organization from any other duty imposed upon it by law for the inspection of donated pharmaceuticals or health care supplies or for any provisions regarding the handling of those products, or relieve any health care provider from liability arising out of the prescription of such pharmaceuticals or health care supplies.

[~~(e) For purposes of this section:~~

~~"Needy person" means any natural person who lacks the means to obtain adequate or proper pharmaceuticals or health care supplies as determined by a practitioner at a Hawaii qualified health center established under section 346-41.5, to be in need of service.~~

~~"Pharmaceuticals and health care supplies" means any medicine (prescription or nonprescription, excluding all controlled substances listed in chapter 329) or health care supplies such as soap, personal sanitary products, baby formula, dietary supplement, health care aids such as thermometers, surgical gloves, or bandages, or any other item that is customarily fit for human consumption or external use, before the expiration date stamped on the product, if any.~~

~~"Pharmaceutical company" means any company that manufactures pharmaceuticals and health care supplies.~~

~~"Pharmacy" is as defined in chapter 461.~~]

(e) No pharmaceutical manufacturer shall be liable for any claim or injury arising from the donation and transfer of any prescription drug pursuant to this chapter, including but not limited to liability for failure to transfer or communicate product or consumer information or expiration date information regarding the transferred drug."

SECTION 8. The department of health shall submit a report to the legislature no later than twenty days prior to the convening of the regular session of 2006 reporting:

(1) Difficulties with the implementation and operation of the prescription drug repository program, if any;
(2) Potential for expansion to include drugs donated by private individuals;
(3) Possible strategies to provide incentives for dispensing pharmacies or institutional facilities to provide donations of prescription drugs to repositories; and
(4) Suggested legislation.

SECTION 9. The return-for-credit-and-reuse of prescription drugs authorized by this Act shall not be implemented until appropriate administrative rules to address the crediting and handling fee processes are adopted and take effect. Returns for full credit with no handling fees of prescription drugs refused on delivery shall not require rulemaking.

SECTION 10. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.[1]

SECTION 11. This Act shall take effect on July 1, 2004, and shall be repealed on July 1, 2010; provided that sections 328C-1, 328C-2, and 461-1, Hawaii Revised Statutes, shall be reenacted in the form in which they read on the day before the effective date of this Act.

(Approved July 9, 2004.)

Note

1. Edited pursuant to HRS §23G-16.5.