

**10 GCA HEALTH AND SAFETY
CH. 5 THE MEDICINE BANK ACT OF 2004**

**CHAPTER 5
THE MEDICINE BANK ACT OF 2004**

NOTE: New Chapter 5 added by P.L. 27-122:2.

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§ 5101. Title.

Chapter 5, Division 1 of Title 10, GCA is herein referred to as the 'Medicine Bank Act of 2004.'

§ 5102. Definitions.

Whenever used in this Chapter or unless the context otherwise requires, the following definitions shall apply.

(a) 'Charitable, religious, or nonprofit organization' means any organization which was organized and is operating on Guam for charitable or religious purposes or to promote social welfare, which is exempt from income taxation under 501(c) 3 of the United States Internal Revenue Code and which distributes pharmaceuticals and health care supplies at no cost to needy persons.

(b) 'Director' shall mean the Director of the Department of Public Health and Social Services. The Director shall also serve as the Medicine Bank Director or if he is unable to do so, he shall authorize a licensed pharmacist or another individual with the qualifications and knowledge of receiving, distributing, or storing pharmaceuticals, to administer the Medicine Bank.

(c) 'Institutional facility' means a government owned and operated:

- (1) Hospital;
- (2) Convalescent home;
- (3) Nursing home;

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- (4) Extended care facility;
- (5) Mental institution;
- (6) Rehabilitation center;
- (7) Health maintenance organization;
- (8) Psychiatric center;
- (9) Mental retardation center;
- (10) Penal institution; or

(11) Any other government-owned organization or facility whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, except those places where physicians, dentists, veterinarians, osteopaths, podiatrists, or other prescribers are duly licensed to engage in exclusively private practice.

(d) 'Eligible Person' means any person as defined by the Medically Indigent Program ("MIP") for Guam and the Medicaid Poverty Guidelines.

(e) 'Pharmaceuticals and health care supplies' means any medicine prescription or nonprescription, excluding all controlled substances listed in Title 9, GCA Chapter 67, the Uniform Controlled Substance Act; 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 which is fit for human consumption or external use, before the expiration date stamped on the product.

(f) 'Pharmaceutical company' means any company that manufactures pharmaceuticals and health care supplies or distributes such items.

(g) 'Pharmacy' means any place on Guam where drugs are dispensed and pharmaceutical care is provided to residents of Guam, or as further defined in the Guam Code Annotated Title 10, The Guam Pharmacy Practice Act.

(h) 'Pharmacist' means an individual licensed on Guam to practice his/her profession and any other person (e.g., pharmacist intern) authorized by Guam law to practice under the supervision of a pharmacist licensed on Guam and in the practice of pharmacy as defined in the Guam Code Annotated Title 10, The Guam Pharmacy Act.

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(i) 'Licensed Practitioner', for purposes of this Act, shall mean a physician, nurse, dentist, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted by Guam law, to distribute, dispense, administer or prescribe drugs in accordance with the Guam Code Annotated Title 10, The Guam Pharmacy Practice Act and other applicable Guam law(s).

(j) 'Prescription', means an order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g. an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription) and as defined by Guam Code Annotated Title 10, The Guam Pharmacy Act.

§ 5103. Creation of a Medicine Bank.

There is hereby created within the Guam Department of Public Health and Social Services a 'Medicine Bank'.

(a) The purpose of the Medicine Bank is to collect donations of pharmaceuticals and health care supplies and distribute them to Community Health Centers and to various institutional facilities that are government owned and operated as defined in Section 5102 of this Chapter for distribution by the Community Health Centers and these institutional facilities and for dispensing to eligible individuals in need as defined by this Chapter, the Guam MIP law or the Medicaid Poverty Guidelines.

(b) The Medicine Bank is an agent for collection and distribution of such donations to Community Health Centers and other government owned institutional facilities as defined in this Chapter, but not for purposes of filling individual prescriptions for eligible persons. These donations have no actual cash value and can not be considered a liquid asset or inventory. Thus, circumstances affecting the Medicine Bank may necessitate the charging of administrative fees for the distribution of materials. In accordance with the Administrative Adjudication Act, the Director shall determine the fee amount necessary to ensure the continuance of the Medicine Bank and shall promulgate these rules and regulations within ninety (90) days after the enactment of this Act. The Director of the Department of Public Health and Social Services shall assess these fees onto the receiving entities requesting for medicines and supplies and not to eligible individuals. Government institutional facilities, as defined in this Chapter, and any other entity receiving medicines and supplies from the

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Medicine Bank shall not charge or pass the cost of these medicines and supplies onto the eligible individual(s).

(c) The Medicine Bank shall ensure that all material, including prescription drugs, non-prescription drugs, over the counter drugs, medical supplies, and other items shall be identified, dated, and transported to the Medicine Bank in accordance with accepted and required standards established by Guam law, Federal law and/or Federal guidelines to include the United States, Food and Drug Administration. Upon receipt by the Medicine Bank, all medicines and materials will be examined and inspected carefully by the Director of the Department of Public Health and Social Services, or his lawful designee, as the Medicine Bank Director, before further distribution to the Community Health Centers or to the various institutional facilities that are government owned and operated as defined in Section 5102 of this Chapter for the lawful dispensing by these institutional facilities to eligible individuals.

(d) The Medicine Bank shall ensure that each incoming delivery of prescription drugs and other medicines and materials shall be examined to ensure that factory seals are intact. Any products that are found to be damaged, outdated, deteriorated, misbranded, or adulterated, shall be isolated until they can be discarded in accordance with Guam law, Federal law or Federal guidelines.

(e) The Medicine Bank shall ensure that all donated medications will be labeled as required by Guam law, or in the absence of such law then Federal law shall apply. No medication which has been previously dispensed by a practitioner to a private citizen will be accepted. Materials received which are not prescription medicines such as over-the-counter medicines, home health equipment, medical supplies, and any other items, shall also be carefully inspected upon receipt. They must be judged fit for use before being distributed or will be properly disposed of in accordance with Guam law. The Director of the Department of Public Health and Social Services, or his lawful designee, the Medicine Bank Director, in accordance with the Administrative Adjudication Act, shall promulgate rules and regulations and guidelines they deem necessary and appropriate to minimize government liability for distribution of medical equipment. Such rules and regulations may require that medical equipment and supplies are received with the proper and correct operating manual, documentation of maintenance history associated with the equipment, and in the instances in which the equipment is new or never used, the Medicine Bank may require

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that factory information be provided. Proper rules and regulations should be established to ensure that the government and the Medicine Bank shall not be held liable for problems that arise from the use or operation of these items.

(f) The Medicine Bank Director shall ensure that the rooms where the Medicine Bank storage is located shall be secure from unauthorized entry. The Medicine Bank storage rooms are to be entered through a locked door, and keys are to be held only by the Pharmacy Staff and the Medicine Bank Director. The area must be well-lighted and the building must be locked and guarded by security personnel at all times. No controlled substances will be handled by the Medicine Bank. No clients or patients or eligible individuals will come to, or receive donated medicines or materials directly from the Medicine Bank. Dispensing of medicines and supplies received from the Medicine Bank will take place only at Community Health Centers or mobile health units, or the various institutional facilities that are government owned and operated as defined in Section 5102 of this Chapter for the lawful dispensing by these institutional facilities to eligible individuals, and where the pharmaceuticals will be dispensed by licensed practitioners.

(g) All drugs, including prescription drugs without special storage requirements, shall be stored according to United States Pharmacopoeia recommendations, as stated in Chapter 328, or in accordance with accepted standards regarding conditions and temperatures for the storage of drugs.

(h) Careful inventory of all donated pharmaceuticals and other materials shall be maintained and updated, as necessary, upon receipt and distribution. Medicines, and other pharmaceutical supplies and equipment leaving the Medicine Bank will be double-checked for damage and proper identity. Because medications are donated to the Medicine Bank by many sources, including local doctors' offices, pharmacies, religious and charitable organizations, the Medicine Bank shall ensure that upon receipt, each medication will be added to the inventory list with the name and address of the donor, date of donation, name of medication, strength, lot number, quantity, and expiration date. Full inventories of available medications will be made available to the Community Health Centers and the various institutional facilities that are government owned and operated as defined in Section 5102 of this Chapter, on a regular basis. Community Health Centers and the various institutional facilities that are government owned and operated as defined in Section 5102 of this Chapter, shall then place orders with the Medicine Bank for the medicines available at that

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time. The Medicine Bank will generate a dated record of each distribution to each health center or institutional facility. Oldest stock will be distributed first. Older drugs will be rotated to the front of the shelf as new drugs of the same type are received.

As distributions of medicine are made to each participating site, receiving staff will check the distribution against a packing list, sign and fax the list back to the Medicine Bank Director. Medicines shall be dispensed by licensed practitioners at the receiving sites.

Medications close to expiration will be distributed only if the requesting health center or institutional facility assures the Medicine Bank staff that the medications are for immediate dispensing and will be consumed by the patient prior to the expiration date. All outdated drugs will be isolated from other drugs and disposed of according to applicable Guam or Federal laws. The inventory record for all outdated drugs will note the disposal or return to manufacturer of each item, and such records shall be maintained for five (5) years as required by Guam and or Federal laws.

The Director of the Department of Public Health and Social Services, or his designee, the Medicine Bank Director, and the appropriate staff shall, conduct a physical inventory several times a year and reconciled with computer inventory records. If a discrepancy is found between the physical and computer inventories, the physical count is definitive. At such times, the computer count may be adjusted to reflect the true count. A list of changes to the computer inventory will be kept and periodically reviewed. Special attention will be paid to instances when the same item repeatedly appears to be short, when only expensive items appear to be missing, where inventory consistently indicates shortages more than overages, or when a pattern of discrepancy emerges at particular times or when particular staff are on duty. At these times, an investigation shall be conducted by the Medicine Bank Director with the assistance of the Guam Police Department.

(i) The Medicine Bank shall comply promptly with all recalls and withdrawals of prescription drugs and over the counter drugs (OTC). Notices of recall or withdrawal of prescription drugs and over the counter drugs are periodically issued by the U. S. Department of Health, the Food and Drug Administration, other Federal, state, or local government agencies, and manufacturers. Additionally, notices of any action undertaken to protect public health and safety, may also be issued by responsible parties. When these notices are received by the Community Health Centers,

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the various institutional facilities that are government owned and operated as defined in Section 5102 of this Chapter for purposes of receiving medicines and supplies from the Medicine Bank, the Department of Public Health and Social Services or the pharmacy, the Pharmacist shall immediately notify the Director of the Medicine Bank, and any affected medicines or other items will be immediately removed from the inventory and destroyed or returned to the supplier. In addition, the Medicine Bank will notify the health centers and the various institutional facilities as defined in Section 5102 that may have received such pharmaceutical or other items from the Medicine Bank, that such pharmaceutical or item is the subject of a recall or withdrawal.

(j) The Medicine Bank will follow disaster plans that are in place for the Department of Public Health and Social Services or other government of Guam agencies. These complete disaster plans will be made available for review in the Medicine Bank Pharmacy and will be carefully followed in the event of an emergency. In addition, the Medicine Bank shall develop and implement special procedures which will address the security of the drugs and pharmaceuticals stored in the Medicine Bank.

Should a crisis occur when the Medicine Bank is closed and no personnel are on duty, the Medicine Bank Pharmacist will be notified immediately by the Medicine Bank staff or Public Health officials. The Medicine Bank Director will also be notified immediately. Either or both of these people will go to the Medicine Bank promptly to assess damage.

If there is physical damage that compromises the integrity of the room in which drugs are stored, all drugs will be immediately removed and relocated to a secure place. If the room appears to continue to be safe, secure and clean, the Medicine Bank will remain where it is.

If the crisis causes the temperature to exceed, or go below permitted levels, all drugs will be discarded. Likewise, all medication damaged by water or fire will be discarded. Any container, which appears to be damaged in any way, will be discarded. All medications discarded will be disposed of properly.

(k) The Medicine Bank office shall establish and maintain a current list of all persons responsible for the distribution, storage and handling of prescription drugs.

A current list of responsible persons, including the Medicine Bank Pharmacist, the Medicine Bank Director, and any other necessary persons will be maintained by the Medicine Bank, including a description of each

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person's duties with regard to the Medicine Bank, as well as a brief summary of each person's qualifications. This list will be available for review at all times.

(l) The Director of the Department of Public Health and Social Services shall serve as the Medicine Bank Director or if he is unable to do so, he shall authorize a licensed pharmacist or another individual with the qualifications and knowledge of receiving, distributing, or storing pharmaceuticals, to administer the Medicine Bank.

The Director shall, as he deems necessary and fit to ensure the continuity and meet the services of the Medicine Bank, establish administrative fees, promulgate rules, policies, procedures or regulations in accordance with this Chapter while adhering to the procedures of the Guam Administrative Adjudication Act.

§ 5104. Exceptions to Liability.

(a) A charitable, religious, or nonprofit organization which in good faith receives pharmaceuticals or health care supplies fit for human consumption or external use, and donates them at no charge to the Medicine Bank, shall not be liable for any civil damages or criminal penalties resulting from the use of the pharmaceuticals or health care supplies distributed or dispensed to eligible persons unless an injury or illness results to those eligible persons as a result of that organization's gross negligence or wanton acts or omissions. Wanton Acts or omissions are as defined and determined by Guam law or in the absence of such law, Federal law shall apply.

(b) Any pharmacy, wholesale prescription drug distributor, pharmaceutical company, institutional facility, or practitioner that in good faith provides pharmaceuticals and health care supplies to the Medicine Bank 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 or previously dispensed prescription drug:

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

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(2) Shall have remained at all times in the control of a person trained and certified by Guam law or Federal law 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.

(d) This Section shall not relieve any organization from any other duty imposed upon it by Guam or Federal 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.

§ 5105. Sale of Donated Pharmaceuticals or Health Care Supplies, Prohibited; Fines and Punishment.

(a) Other than the Medicine Bank, no person or organization shall sell, or offer for sale, any pharmaceutical or health care supply donated or distributed by the Medicine Bank under this Chapter. The Director of the Department of Public Health and Social Services is authorized to establish administrative fees to ensure the continuance of the Medicine Bank. These fees will be charge to the receiving entities and not the eligible individuals. The receiving entities shall not pass on the cost, nor charge or assess fees to the eligible individuals to which they dispensed or issued medicines and/or supplies which the entities received from the Medicine Bank.

(b) Any violation of this Section or the entire Medicine Bank Act by any person is punishable as a felony.

§ 5106. Labeling of Donated Pharmaceuticals or Health Care Supplies.

Any charitable, religious, or nonprofit organization which receives and distributes donated pharmaceuticals or health care supplies pursuant to this Chapter shall affix a label upon those items stating that the items are donated and are not for resale and stating that they are fit for human consumption or use on the date that they left control of the charitable, religious, or nonprofit organization.

§ 5107. Government of Guam's Authority to Regulate, Inspect, or Ban the Use of Donated Pharmaceuticals or Health Care Supplies.

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Nothing in this Chapter is intended to restrict the authority of any Government of Guam department to regulate, inspect, or ban the use of donated pharmaceuticals or health care supplies for human consumption or use. Any provisions to the contrary notwithstanding, all activities conducted by an organization under this Chapter involving the distribution of prescription drugs to persons other than a consumer or patient shall be included within the definition of wholesale distribution as defined in the Guam Code Annotated Title 10, The Pharmacy Practice Act.

In addition, the distribution of pharmaceuticals and health care supplies directly to eligible person(s) (consumers or patients) by a charitable, religious, or nonprofit organization pursuant to the Chapter, and the activities associated with that distribution, shall comply with the applicable provisions of the Guam Code Annotated Title 10, the Pharmacy Practice Act, and all other Guam laws which relate to prescription drug wholesalers.
