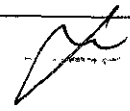


SENATE
S.B. No. 3550

9 DEC -7 AM 15

Introduced by Senator Miriam Defensor-Santiago

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EXPLANATORY NOTE

The Constitution, Article 2, Section 15 provides:

The State shall protect and promote the right to health of the people and instill health consciousness among them.

The Constitution, Article 13, provides:

Section 11. The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the under-privileged, sick, elderly, disabled, women, and children. The State shall endeavor to provide free medical care to paupers.

Section 12. The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems.

According to the World Health Organization, about 10 million people—most of them in low- and middle-income countries—die needlessly every year because they do not have access to existing medicines and vaccines. In the Philippines alone, millions of poor people fall sick and die because they lack access to the diagnostics, vaccines, and medicines needed to identify, prevent, or treat debilitating diseases.

This Bill aims to improve the poor's access to medicines by establishing a Medicine Bank. The Medicine Bank shall collect donations of pharmaceuticals and health care supplies and distribute them to Community Health Centers and to various government-owned and operated institutional facilities for dispensing to poor patients in need of life-saving medicines.


MIRIAM DEFENSOR SANTIAGO

9 DEC -7 AM 1:15

SENATE
S.B. No. **3550**

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Introduced by Senator Miriam Defensor Santiago

1 AN ACT
2 CREATING A MEDICINE BANK

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

3 SECTION 1. *Short Title.* – This Act shall be known as the “Medicine Bank Act of 2009.”

4 SECTION 2. *Declaration of Policy.* – It is hereby declared the policy of the State to
5 protect and promote the right to health of the people. Towards this end, the State shall adopt an
6 integrated and comprehensive approach to health development which shall endeavor to make
7 essential goods, health, and other social services available to all the people at affordable cost.
8 There shall be priority for the needs of the under-privileged, sick, elderly, disabled, women, and
9 children. The State shall endeavor to provide free medical care to paupers. The State shall also
10 establish and maintain an effective drug regulatory system responsive to the country’s health
11 needs and problems.

12 SECTION 3. *Definitions.* – In this Act, the term –

13 (a) “Charitable, religious, or nonprofit organization” means any organization which is
14 organized and is operating for charitable or religious purposes or to promote social welfare, and
15 which distributes pharmaceuticals and health care supplies at no cost to needy persons;

16 (b) “Secretary” means the Secretary of Health. The Secretary shall also serve as
17 the Medicine Bank Director or if he or she is unable to do so, he or she shall authorize a

1 licensed pharmacist or another individual with the qualifications and knowledge of receiving,
2 distributing, or storing pharmaceuticals, to administer the Medicine Bank;

3 (c) "institutional facility" means a government owned and operated: (1) Hospital;
4 (2) Convalescent home; (3) Nursing home; (4) Extended care facility; (5) Mental institution;
5 (6) Rehabilitation center; (7) Health maintenance organization; (8) Psychiatric center; (9)
6 Mental retardation center; (10) Penal institution; or (11) Any other government-owned
7 organization or facility whose primary purpose is to provide a physical environment for
8 patients to obtain health care services or at-home care services, except those places where
9 physicians, dentists, veterinarians, osteopaths, podiatrists, or other prescribers are duly licensed
10 to engage in exclusively private practice;

11 (d) "eligible person" means any eligible person as defined by rules and regulations to
12 be issued by the Secretary;

13 (e) "pharmaceuticals and health care supplies" means any medicine prescription or
14 nonprescription, excluding all controlled substances listed under appropriate laws; or health care
15 supplies such as soap, personal sanitary products, baby formula, dietary supplement, health care
16 aids such as thermometers, surgical gloves, or bandages, or any other item which is fit for
17 human consumption or external use, before the expiration date stamped on the product;

18 (f) "pharmaceutical company" means any company that manufactures
19 pharmaceuticals and health care supplies or distributes such items;

20 (g) "pharmacy" means any place in the Philippines where drugs are dispensed and
21 pharmaceutical care is provided;

22 (h) "pharmacist" means an individual licensed to practice pharmacy in the
23 Philippines;

24 (i) "licensed practitioner," for purposes of this Act, means a physician, nurse,
25 dentist, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise
26 permitted by law, to distribute, dispense, administer, or prescribe in accordance with law;

27 (j) "prescription" means an order for medication which is dispensed to or for an
28 ultimate user, but does not include an order for medication which is dispensed for immediate

1 administration to the ultimate user (e.g. an order to dispense a drug to a bed patient for
2 immediate administration in a hospital is not a prescription) and as defined by law.

3 SECTION 4. *Creation of a Medicine Bank.* – There is hereby created within the
4 Department of Health a “Medicine Bank.”

5 (a) The purpose of the Medicine Bank is to collect donations of pharmaceuticals
6 and health care supplies and distribute them to Community Health Centers and to various
7 institutional facilities that are government owned and operated for distribution by the
8 Community Health Centers and these institutional facilities and for dispensing to eligible
9 individuals in need as defined pursuant to this Act.

10 (b) The Medicine Bank is an agent for collection and distribution of such
11 donations to Community Health Centers and other government owned institutional facilities as
12 defined in this Act, but not for purposes of filling individual prescriptions for eligible
13 persons. These donations have no actual cash value and cannot be considered a liquid asset
14 or inventory. Thus, circumstances affecting the Medicine Bank may necessitate the charging
15 of administrative fees for the distribution of materials. The Secretary shall determine
16 the fee amount necessary to ensure the continuance of the Medicine Bank and shall
17 promulgate these rules and regulations within ninety (90) days after the enactment of
18 this Act. The Secretary shall assess these fees onto the receiving entities requesting for
19 medicines and supplies and not to eligible individuals. Government institutional facilities, as
20 defined in this Act, and any other entity receiving medicines and supplies from the
21 Medicine Bank shall not charge or pass the cost of these medicines and supplies onto the
22 eligible individual(s).

23 (c) The Medicine Bank shall ensure that all material, including prescription drugs,
24 non-prescription drugs, over-the-counter drugs, medical supplies, and other items shall be
25 identified, dated, and transported to the Medicine Bank. Upon receipt by the Medicine
26 Bank, all medicines and materials will be examined and inspected carefully by the Secretary,
27 or his or her lawful designee, as the Medicine Bank Director, before further distribution to
28 the Community Health Centers or to the various institutional facilities that are government

1 owned and operated for the lawful dispensing by these institutional facilities to eligible
2 individuals.

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

8 (e) The Medicine Bank shall ensure that all donated medications will be labeled as
9 required by law. No medication which has been previously dispensed by a practitioner to a
10 private citizen will be accepted. Materials received which are not prescription medicines such
11 as over-the-counter medicines, home health equipment, medical supplies, and any other items,
12 shall also be carefully inspected upon receipt. They must be judged fit for use before being
13 distributed or will be properly disposed of in accordance with law. The Secretary shall
14 promulgate rules and regulations and guidelines he or she deems necessary and appropriate to
15 minimize government liability for distribution of medical equipment. Such rules and
16 regulations may require that medical equipment and supplies are received with the proper
17 and correct operating manual, documentation of maintenance history associated with the
18 equipment, and in the instances in which the equipment is new or never used, the Medicine
19 Bank may that factory information be provided. Proper rules and regulations should be
20 established to ensure that the government and the Medicine Bank shall not be held liable for
21 problems that arise from the use or operation of these items.

22 (f) The Medicine Bank Director shall ensure that the rooms where the Medicine
23 Bank storage is located shall be secure from unauthorized entry. The Medicine Bank storage
24 rooms are to be entered through a locked door, and keys are to be held only by the Pharmacy
25 Staff and the Medicine Bank Director. The area must be well-lighted and the building must be
26 locked and guarded by security personnel at all times. No controlled substances will be handled
27 by the Medicine Bank. No clients or patients or eligible individuals will come to, or receive
28 donated medicines or materials directly from the Medicine Bank. Dispensing of medicines
29 and supplies received from the Medicine Bank will take place only at Community Health

1 Centers or mobile health units, or the various institutional facilities that are government owned
2 and operated as defined under this Act for the lawful dispensing by these institutional
3 facilities to eligible individuals, and where the pharmaceuticals will be dispensed by licensed
4 practitioners.

5 (g) All drugs, including prescription drugs without special storage requirements,
6 shall be stored according to rules and regulations, or in accordance with accepted standards
7 regarding conditions and temperatures for the storage of drugs.

8 (h) Careful inventory of all donated pharmaceuticals and other materials shall be
9 maintained and updated, as necessary, upon receipt and distribution. Medicines, and other
10 pharmaceutical supplies and equipment leaving the Medicine Bank shall be double-checked
11 for damage and proper identity. Because medications are donated to the Medicine Bank by
12 many sources, including local doctors' offices, pharmacies, religious and charitable
13 organizations, the Medicine Bank shall ensure that upon receipt, each medication will be
14 added to the inventory list with the name and address of the donor, date of donation,
15 name of medication, strength, lot number, quantity, and expiration date. Full inventories
16 of available medications shall be made available to the Community Health Centers and the
17 various institutional facilities that are government owned and operated on a regular basis.
18 Community Health Centers and the various institutional facilities that are government owned
19 and operated shall then place orders with the Medicine Bank for the medicines available at
20 that time. The Medicine Bank shall generate a dated record of each distribution to each health
21 center or institutional facility. Oldest stock shall be distributed first. Older drugs shall be
22 rotated to the front of the shelf as new drugs of the same type are received.

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

26 Medications close to expiration shall be distributed only if the requesting
27 health center or institutional facility assures the Medicine Bank staff that the medications
28 are for immediate dispensing and shall be consumed by the patient prior to the expiration
29 date. All outdated drugs shall be isolated from other drugs and disposed of according to

1 applicable laws or regulations. The inventory record for all outdated drugs shall note the
2 disposal or return to manufacturer of each item, and such records shall be maintained for five
3 (5) years as required by law.

4 The Secretary, or his or her designee, the Medicine Bank Director, and the appropriate
5 staff shall, conduct a physical inventory several times a year and reconcile with computer
6 inventory records. If a discrepancy is found between the physical and computer inventories,
7 the physical count is definitive. At such times, the computer count may be adjusted to
8 reflect the true count. A list of changes to the computer inventory shall be kept and
9 periodically reviewed. Special attention shall be paid to instances when the same item
10 repeatedly appears to be short, when only expensive items appear to be missing, where
11 inventory consistently indicates shortages more than overages, or when a pattern of
12 discrepancy emerges at particular times or when particular staff are on duty. At these times,
13 an investigation shall be conducted by the Medicine Bank Director with the assistance of the
14 National Bureau of Investigation.

15 (i) The Medicine Bank shall comply promptly with all recalls and withdrawals
16 of prescription drugs and over-the-counter drugs. Notices of recall or withdrawal of
17 prescription drugs and over the counter drugs are periodically issued by the Department of
18 Health, other government or local government agencies, and manufacturers. Additionally,
19 notices of any action undertaken to protect public health and safety, may also be issued by
20 responsible parties. When these notices are received by the Community Health Centers, the
21 various institutional facilities that are government owned and operated, or the Department of
22 Health, the Pharmacist shall immediately notify the Director of the Medicine Bank, and any
23 affected medicines or other items shall be immediately removed from the inventory and
24 destroyed or returned to the supplier. In addition, the Medicine Bank shall notify the health
25 centers and the various government institutional facilities that may have received such
26 pharmaceutical or other items from the Medicine Bank, that such pharmaceutical or item is the
27 subject of a recall or withdrawal.

28 (j) The Medicine Bank shall follow disaster plans that are in place for the
29 Department of Health or other government agencies. These complete disaster plans shall be

1 made available for review in the Medicine Bank Pharmacy and shall be carefully followed in
2 the event of an emergency. In addition, the Medicine Bank shall develop and implement
3 special procedures which will address the security of the drugs and pharmaceuticals stored
4 in the Medicine Bank.

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

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

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

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

20 A current list of responsible persons, including the Medicine Bank Pharmacist, the
21 Medicine Bank Director, and any other necessary persons shall be maintained by the
22 Medicine Bank, including a description of each person's duties with regard to the
23 Medicine Bank, as well as a brief summary of each person's qualifications. This list
24 shall be available for review at all times.

25 SECTION 5. *Exceptions to Liability.* – (a) A charitable, religious, or nonprofit
26 organization which in good faith receives pharmaceuticals or health care supplies fit
27 for human consumption or external use, and donates them at no charge to the Medicine Bank,
28 shall not be liable for any civil damages or criminal penalties resulting from the use

1 of the pharmaceuticals or health care supplies distributed or dispensed to eligible persons
2 unless an injury or illness results to those eligible persons as a result of that organization's gross
3 negligence or wanton acts or omissions

4 (b) Any pharmacy, wholesale prescription drug distributor, pharmaceutical
5 company, institutional facility, or practitioner that in good faith provides pharmaceuticals
6 and health care supplies to the Medicine Bank without remuneration or expectation of
7 remuneration, shall be exempt from civil liability for injuries and damages resulting from
8 their acts or omissions in providing pharmaceuticals and health care supplies, except for gross
9 negligence, or wanton acts or omissions on the part of the pharmacy, wholesale prescription
10 drug distributor, pharmaceutical company, institutional facility, or practitioner.

11 (c) Any donated or previously dispensed prescription drug:

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

13 (2) Shall have remained at all times in the control of a person trained and
14 certified by law, rule, or regulation in the storage and administration of drugs
15 in institutional facilities;

16 (3) Shall not have been adulterated, misbranded, or stored under conditions
17 contrary to standards established by law, rule, or regulation or the product
18 manufacturer; and

19 (4) Shall be used before the expiration date on the unit.

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

25 SECTION 6. *Prohibition on Sale of Donated Pharmaceuticals or Health Care*
26 *Supplies.* – (a) Other than the Medicine Bank, no person or organization shall sell, or offer for
27 sale, any pharmaceutical or health care supply donated or distributed by the Medicine
28 Bank under this Act.

1 (b) Any person who violates this section shall be punished by imprisonment of one
2 (1) year and a fine of ten thousand pesos (P10,000.00).

3 SECTION 7. *Labeling of Donated Pharmaceuticals or Health Care Supplies.* – Any
4 charitable, religious, or nonprofit organization which receives and distributes donated
5 pharmaceuticals or health care supplies pursuant to this Act shall affix a label upon those
6 items stating that the items are donated and are not for resale and stating that they are
7 fit for human consumption or use on the date that they left control of the charitable,
8 religious, or nonprofit organization.

9 SECTION 8. *Rules and Regulations.* – The Secretary of Health shall issue the necessary
10 rules and regulations to carry out the objectives of this Act.

11 SECTION 9. *Separability Clause.* – If any provision, or part hereof is held invalid or
12 unconstitutional, the remainder of the law or the provision not otherwise affected shall remain
13 valid and subsisting.

14 SECTION 10. *Repealing Clause.* – Any law, presidential decree or issuance, executive
15 order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent
16 with, the provisions of this Act is hereby repealed, modified, or amended accordingly.

17 SECTION 11. *Effectivity Clause.* – This Act shall take effect fifteen (15) days after its
18 publication in at least two (2) newspapers of general circulation.

Approved,

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