



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

April 14, 2004

ADMINISTRATIVE ORDER  
No. 144 s. 2004

**SUBJECT: Guidelines for the Establishment and Operations of Botika ng Barangays (BnB) and Pharmaceutical Distribution Networks (PDNs)**

**I. RATIONALE**

It is the policy of the State to protect and promote the right to health of the people. Particularly, the State, under Section II of Article XIII of the 1987 Philippine Constitution, is mandated to adopt an "integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services acceptable to all the people at affordable cost".

Meanwhile, Republic Act No. 6675, otherwise known as the Generic Act of 1988, prescribes that it is the policy of the State to "ensure the adequate supply of drugs with generic names at the lowest possible cost".

Further, the Local Government Code of 1991, particularly under Rule XIII of its Implementing Rules and Regulations, prescribes the kind of relationship between the Local Government Units (LGUs) and Peoples' Organizations (POs), Non-Government Organizations (NGOs) and Private Sector that may exist within the framework of devolution, and the latter's role as partners in the delivery of basic services.

Pursuant thereto, the Department of Health (DOH) crafted several issuances to implement and actualize the objectives of said State policies and aforementioned laws.

Accordingly, the DOH issued Administrative Order No. 23-A., dated 05 July 1996, that outlines the guidelines on the development and establishment of Botika ng Barangay (BnB) and Administrative Order No. 70, dated 03 January 2002, that provides for licensing procedures for Botika ng Barangays under the supervision of a registered pharmacist and with the support of the Local Government Units.

Recognizing further the vital role of the Private Sector and the Third Sector (Non-Government Organizations, People's Organization, Community Based Organizations, Cooperatives, and the likes), Administrative Order No. 159 dated 07 October 2002 was issued to provide policy guidelines and procedures for the utilization of financial assistance for the purchase of BnB drugs through the registration of Pharmaceutical Distribution Networks (PDNs).

The opening of opportunity to the people by way of the availability of Standby Funds from the Philippine Charity Sweepstakes Office (PCSO) and through partnership with the Philippine International Trading Corporation (PITC) as a procurement agent prompted the DOH to issue Administrative Order No. 64 dated 01 July 2003. The issuance caused the strengthening of the Centers for Health Development (CHDs) as vital instruments of the State and the DOH in establishing BnBs within their area of responsibility. The issuance further provided the specific mechanisms on how the funds will be utilized and how to sustain the operations of the BnBs.

The bullish promotion and advocacy of the BnBs by the CHDs and the DOH, created a ripple in the health sector, and several strategic partnerships were thereafter created between the DOH and several stakeholders. Among the partners recognized by the DOH are the Technology and Livelihood Resource Center, the Department of Labor and Employment, Botika Binhi (per Department Order No. 275-G s. 1994), and the National Pharmaceutical Foundation.

Thereafter, a review of the DOH's effort to expand and sustain the BnBs was conducted. The assessment disclosed that the several issuances that were used as basis for the establishment and operations of the BnBs needed to be revised and integrated into an omnibus Administrative Order to establish uniformity and sustainability in policies and procedures.

The existing guidelines promulgated under Administrative Order No. 70 s. 2002 for the issuance of a Botika ng Barangay Special License to Operate (BnB SLTO), in particular, were rationalized, re-examined and reviewed. Such reviews include analyses on the operational consequences of its provisions.

The review revealed that some of the requirements in the provisions of the subject issuance, i.e., unnecessary layers in the approval and reporting process, undefined specifications and standards, and undefined timelines in the decision-making process, may be considered as mere procedural barriers impeding immediate accessibility and delivery of drugs and medicines.

Therefore, in accordance with the provisions of Republic Act No. 3720, as amended, otherwise known as the Food, DrUgs, Devices and Cosmetics Act, and in order to establish, consolidate, and sustain the BnBs, as well as to streamline and simplify the BnB licensing system and to achieve the clarion call for the reduction of the cost of drugs and medicines, this omnibus Administrative Order is hereby issued.

## II. OBJECTIVES

The objectives of this Order are as follows:

1. To promote equity in health by ensuring the availability and accessibility of affordable, safe and effective, quality essential drugs to all, with priority for marginalized, underserved, critical and hard to reach areas;

2. To integrate all related issuances of the DOH that provides rules and regulations in the establishment and operations of BnBs; and
3. To define the roles and responsibilities of the different units of the DOH and other partners from the different sectors in facilitating and regulating the establishment of BnBs.

### III. DEFINITION OF TERMS

As used in this Administrative Order, the terms herein shall be understood to mean as follows:

1. Botika ng Barangay (BnB) - refers to a drug outlet managed by a legitimate community organization (CO)/non- government organization (NGO) and/or the Local Government Unit (LGU), with a trained operator and a supervising pharmacist specifically established in accordance with this Order. The BnB outlet should be initially identified, evaluated and selected by the concerned Center for Health Development (CHD), approved by the PHARMA 50 Project Management Unit (PMU), and specially licensed by the Bureau of Food and Drugs (BFAD) to sell, distribute, offer for sale and/or make available low-priced generic home remedies, over-the-counter (OTC) drugs and two (2) selected, publicly-known prescription antibiotic drugs (i.e., Amoxicillin and Cotrimoxazole).
2. Pharma 50 Project Management Unit (PHARMA 50 PMU) - a unit created and established by the DOH to Operationalize, manage and monitor the implementation of all DOH initiatives, programs and projects, (including but not limited to the Parallel Drug Importation Project for DOH Botikas, Botika ng Barangay, Pharmaceutical Distribution Networks, Drug Consignment, etc) which paramount objective is to achieve the reduction of the price of drugs and medicines.
3. BnB Operator - refers to a trained volunteer health worker on the BnB standards of operating and managing a BnB outlet under the supervision of a registered pharmacist. In order to sustain the operations of the BnB, there should be at least two (2) trained volunteers for every BnB outlet. The BnB Operator will be trained and have to be registered by the DOH, through the concerned CHD, to serve far-flung barangays and/or indigent, depressed areas in the country.
4. Center for Health Development (CHD) - an Office of the Department of Health, headed by a Director who acts as the alter ego of the Secretary of Health, which is responsible in undertaking Public Health Operations, Health Regulatory Functions and other roles and responsibilities within a defined administrative and geographical boundary as embodied and implied in Executive Order 102.
5. Community Organization (CO) or Non-Government Organization (NGO) - refers to a community-based organization that sponsors the establishment of a BnB outlet and that is registered either as a cooperative with the Cooperative Development Authority (CDA), or a foundation/association registered with the Securities Exchange Commission (SEC), or a worker's association registered with the Department of Labor and Employment (DOLE), or any other form of people's organization that is duly registered with and certified by the concerned government agency. The CO or NGO must be represented by a set of officers who must not personally profit

from the operations of the BnB.

6. Department of Health (DOH) - a National Government Agency, the principal agency that regulates and controls the distribution and sale of drugs and medicines to outlets such as the BnBs.

7. Local Government Unit (LGU) - refers to the territorial and political subdivision of the Republic of the Philippines as defined in the Local Government Code.

8. Memorandum of Agreement (MOA) - refers to the agreement between and among the DOH, through the concerned CHD; the LGU, represented by its local health officer; and the CO or NGO, for the purpose of providing increased access to low priced, generic home remedies, OTC drugs and 2 pre-selected antibiotic prescription drugs through the BnB. It also refers to an agreement between the DOH and fund source like the PCSO, and procurement agents like the PITC and other stakeholders like the PDNs which define the relationship and technical assistance mutually enjoyed by the parties.

9. Pharmaceutical Distribution Network (PDN) - a non-profit, non-stock, non-government organization licensed by BFAD as a drug distributor or supplier (carrying only generic drugs) and has a list of BnBs as a network of beneficiaries or partners. The PDN has a resident pharmacist as drug distributor and a separate supervising pharmacist(s) for its network of Botika ng Barangays.

10. Supervising Pharmacist - refers to a licensed pharmacist who shall be responsible for the quality standards in the operation of the BnB. He/she may be a private, licensed pharmacist, practicing as a pharmacist or not, directly hired by the BnB or by the LGU, CO or NGO concerned, to supervise as many BnB outlets as the Food Drug Regulation Officer (FDRO) may deem possible based on his/her workload. In case the private, licensed pharmacist is a practicing pharmacist, he/she may only supervise the BnB outlet outside the working hours of his/her pharmacy/drug establishment. The supervising pharmacist may also be a government pharmacist currently employed in the nearest government hospital designated to oversee/supervise the BnB outlet. In the same manner, the government pharmacist may only supervise the BnB outlet outside his/her working hours.

11. Supervising Hours - refers to the length of time a Supervising Pharmacist should stay in the BnB outlet and the frequency of the supervisory visits, which should at least be two (2) working hours per visit for every two (2) weeks or twice a month.

#### IV. GENERAL GUIDELINES

1. The DOH shall prepare specific and separate MOA for every fund and technical assistance and cooperation that it receives for the establishment of BnBs. It shall explicitly identify the procurement agent (if BnB drugs or items will be procured), the source of such funds/technical assistance/cooperation, the conditions for the utilization of the funds/technical assistance/cooperation, and the intended specific beneficiaries, if any.

2. The DOH shall determine the specifications, quantities and allocation of over-the-counter generic

drugs and two (2) selected prescription drugs (Cotrimoxazole and Amoxicillin) in accordance with Executive Order No. 49 (use of latest edition of Philippine National Drug Formulary Volume I as procurement basis for government procurement agents) or in accordance with actual demand patterns as a consequence of morbidity/mortality, population and patients preference trends (for non-government procurement agents) subject to the review and approval of the National Formulary Committee.

3. The CHD, in coordination with BFAD, shall be responsible in identifying and evaluating the BnB applicants that have passed all documentary, legal, and regulatory requirements, as directed in this Order.

4. Each BnB shall be allocated a unit package of drugs and medicines, the equivalent price and combination of quantities of which shall be determined by the DOH and subject to the availability of funds.

5. The CHD shall assure that the necessary structural arrangements such as the assigning of personnel and the creation of a functional committee for the purpose of coordination and monitoring are clearly identified and established.

6. The DOH PHARMA 50 PMU, with the Technical Working Group (TWG) on BnBs, jointly with BFAD and its CHD counterpart (e. g. LHADIDOH Representatives, CHD detailed FDROs and Training Staff), shall provide technical assistance and training to BnB operators/trainors.

7. The BnBs nationwide shall operate within the responsibilities it is bound to perform as prescribed by the DOH and monitored by the CHD/BFAD.

8. The CHD, in coordination with the PHARMA 50 PMU, shall be responsible in conducting centralized price bidding and supplier registration (PITC included, whenever their price list is deemed more advantageous to the Government), which result shall serve as basis for the DOH to enter into contracts for the procurement of future replenishment stocks.

9. The CHDs may allow PDNs operating under their area of responsibility to conduct bidding and awarding of DOH/CHD BnB drug suppliers whenever the circumstance is more advantageous to the public.

10. BnBs shall directly order their BnB drug requirement from the CHD itself or from DOH/CHD registered BnB drug suppliers or authorized distributor (including from PDNs whenever it is more advantageous to the public), and using the approved CHD price. BnBs under the PDNs may also directly order from the CHD itself or from DOH/CHD registered BnB drug suppliers whenever it is more advantageous to the public.

11. Only DOH-CHD Registered Drug Suppliers and the PITC may participate as BnB Suppliers for Stock Replenishments of BnB Drugs and Medicines.

12. BnBs may be established under the initiatives of the CHDs or the PDNs or as an independent initiative by the CO/NGO or the LGUs themselves. BnBs may be directly established by the CHDs or through the PDNs.

13. BnBs may be established even without technical assistance from the DOH, provided that it has proven capacity to adhere on the systems and procedures set by the DOH and has the means and mechanism to support and sustain itself by way of organization, systems, logistics and financial resources. The DOH, through its CHDs, shall therefore determine the relative viability and sustainability of such BnBs and shall apply the usual licensing requirements.

14. The PDN may seek technical assistance from the DOH, and for every specific assistance that the DOH will grant, such must be covered by a separate MOA.

15. Specific steps and procedures not covered by this Order shall be promulgated in the form of Manual of Operations for the BnBs as shall be formulated or disseminated through training and the issuance of an appropriate Department Memorandum.

16. The CHDs shall be authorized to create Revolving Trust Funds for the purpose of receiving remittances from the BnBs and the PDNs for re-ordering BnB drugs subject to the approval of the Department of Budget and Management.

## V. NATURE OF DOH ASSISTANCE

The DOH, through the CHDs, shall encourage and influence communities to establish BnBs in partnership with the LGUs. The DOH is therefore committed to provide the following services for the establishment and management of BnBs on a case to case basis and subject to the availability funds and re-fund:

1. Capability-building assistance like community organizing, training on quality assurance, drug management, purchasing, storage and distribution and training for BnB operators;
2. Information and educational materials on Essential Drugs (e.g., Philippine National Drug Formulary, etc.) and Rational Drug Use;
3. Initial fund or "seed" capital in the form of Drugs and Medicines;
4. Supplemental fund as deemed necessary by the DOH/CHD;
5. Development of a comprehensive BnB Operating Manual which will include topics on Organizational, Financial and Supply Management;
6. Additional fund for traveling expenses (TEV) of government pharmacist for supervision and monitoring subject to availability of funds;

7. Support for monitoring and researches;
8. Legislative support to include review of existing laws and drafting of laws in aid of BnBs; and
9. Methodology and procedures for supervision and monitoring of BnBs.

## VI. BnB LICENSING GUIDELINES

In order to ensure the effectivity and sustainability of the BnB, the regular licensing requirements imposed upon regular drug outlets and pharmacies shall not be expected of the BnB outlets, which shall be subject to special licensing requirements and procedure enumerated hereunder.

### A. Documentary Requirements

The following application documents must be submitted to secure a BnB SLTO:

#### 1. BnB Notarized Petition Form (See Annex A)

The BnB Notarized Petition Form shall be secured from either the Licensing Section of Regulation Division I (Reg. I) of the Bureau of Food and Drugs (BFAD) or the Registration, Licensing and Enforcement Division (RLED) of the nearest CHD.

The BnB Notarized Petition Form must at least contain the following information:

- (a) Registered name and address of the sponsoring CO or NGO, type of organization, if applicable, and name of registering government agency;
- (b) Name, address, and Community Tax Certificate (CTC) particulars of the representative of the CO or NGO sponsoring the BnB outlet;
- (c) Name of the barangays in the city/municipality within the area of coverage by the BnB outlet;
- (d) Name, address, and CTC particulars of the BnB Operator;
- (e) Business hours of the BnB outlet;
- (f) Name, address, Professional Regulation Commission (PRC) particulars, and CTC particulars of the supervising pharmacist;
- (g) Written commitment of the supervising pharmacist to oversee/supervise the BnB outlet;
- (h) Specified supervising hours/scheduled visits of the supervising pharmacist at the BnB outlet,
- (i) Undertaking to display the duly approved BnB SLTO in a conspicuous place within the BnB

outlet;

(j) Undertaking to notify the Reg. I of BFAD or the RLED of CHD in cases of any material change in the information stated in this Petition; and

(k) Signatures of the CO or NGO representative, BnB Operator, and the supervising pharmacist.

## 2. Memorandum of Agreement (See Annex B)

This Agreement must at least show that the BnB is supported by the DOH, through the CHD, the LGU, represented by its local health officer, and the CO or NGO, to ensure the proper management of a BnB that it can provide quality generic drugs at affordable prices.

## 3. Certificate of Attendance/Participation to a training of the BnB Operator

This Certificate shall be issued by the trainers registered by the Department or the CHD concerned.

## 4. Location/Vicinity Map of the BnB outlet

The map should show the location of the BnB outlet.

## B. Procedure

In order to facilitate the issuance of the BnB SLTO, the following guidelines should be observed:

1. The BnB Operator or the sponsoring CO or NGO shall submit all the necessary application documents to the DOH representative (DOH Rep) in the city/municipality where the BnB outlet is located. The DOH Rep, with the FDRO concerned, shall ensure the completeness of the documents and authenticate and process all information thereon. He/she shall likewise schedule an on-site inspection.

During the inspection, the following documents and materials should be made available:

### (a) Premises/Location Site

(i) A wooden or plastic signboard bearing the registered name in front of the BnB outlet in accordance with the specifications provided by Department Memorandum No. 4, dated January 16, 2004;

(ii) A secured, well-ventilated area with concrete or wooden plating; and

(iii) A suitable and proper place for adequate storage of drug products.

### (b) Record Book



(i) Prescription book, containing the following data: name, packaging size, potency, lot number, expiry date and quality of drug product dispensed, name of physician who will issue the prescription, date of purchase, and name of patient; and

(ii) Sales record book.

(c) Reference Materials

(i) Department Memorandum No. 31, series of 2003 or as shall be revised through other Department Memoranda; and

(ii) BnB Drug Guide/Operations Manual.

(d) Other Requirements

(i) File of invoices from the suppliers that indicate the medicines, lot number and expiry date of drugs purchased, pursuant to BFAD Memorandum No. 10, s. 1996; and

(ii) File of prescriptions that should be kept for two (2) years, which may be subject to BFAD inspection.

2. After determining compliance with all the requirements per submitted documents and as established during inspection by the DOH Rep, the FDRO concerned shall forward within three (3) days from receipt of such completed application documents and shall issue an inspection report (signed by both the DOH Rep and the concerned FDRO) to Regulation Division 1 of BFAD and inform the PHARMA 50 PMU of the endorsement thereof. The said reviewed application documents should be covered with an endorsement letter prepared and initialed by the DOH Rep and the concerned FDRO and signed by the CHD Director explicitly stating therein the recommendation to grant a BnB SLTO. The CHD shall maintain file copies of the said documents.

3. Upon receipt of the inspection report, application documents as covered with an endorsement letter, Regulation Division 1 of BFAD shall have a maximum period of five (5) days to process the duly signed BnB SLTO (signed by the BFAD Director) to the CHDs. Upon the signing of the BnB SLTO, the BnB SLTO shall be immediately transmitted to the concerned CHD within five (5) days. Thereafter, the CHD shall distribute the SLTOs to the proper BnB outlet. Regulation Division 1 of BFAD shall then automatically furnish the PHARMA 50 PMU with a list of issued BnB SLTOs per CHD. BFAD shall maintain file copies of the application documents. In the event the BFAD fails to take actions on the CHD endorsed completed documents within the period so prescribed for processing reckoned from the date of receipt of the same documents, the BnB shall be deemed granted with an SLTO.

C. Application/Renewal Fees

1. The Applicant BnB outlet will not be required to pay any fee for the processing of the BnB application by the DoH Rep and the issuance of the BnB SLTO by BFAD.
2. The renewal of the BnB SLTO shall be subject to a fee that shall be determined by the DOH.

#### D. Validity Of The BnB SLTO And Renewal

1. The BnB SLTO shall have an initial validity period of one (1) year from the date of its issuance and shall be deemed renewed every year, unless and until there are CHD and BFAD derogatory findings causing the formal suspension and revocation of SLTO.
2. Application for renewal will only be required for those BnBs with previously suspended or revoked SLTO.

#### E. Grounds For Suspension/Revocation Of BnB SLTO and Consequent Conditions

1. The BnB SLTO, on a case-to-case basis, shall be subject to either suspension or revocation for non-compliance with this Order or any other issuances related herewith.
2. The imposition of either suspension or revocation of the BnB SLTO shall be guided by the non-compliance with this Order and the gravity of the violation committed by the BnB outlet.
3. Upon the revocation of the BnB SLTO, the BnB outlet shall immediately reimburse the equivalent seed money granted to it as an initial capital stock to the government through the concerned CHD.
4. The following are the specific grounds for which a BnB SLTO may be suspended:
  - a) Refuses to allow entry of BFAD inspector;
  - b) Fails to account the lot number and expiry date of drugs on pertinent records;
  - c) Fails to inform BFAD or the CHD of the changes in the circumstances of business including change of supervising pharmacist;
  - d) Increase in the price of drug products sold without the approval of the CHD; and
  - e) Other reasons as shall be determined by the CHD and BFAD.
5. The following are the specific grounds for which a BnB SLTO may be revoked:
  - a) Sells products not approved by the CHD;
  - b) Fails to take necessary remedial or corrective measures within the prescribed measure derogatory

findings as directed by BFAD or the CHD; and

c) Other reasons as shall be determined by the CHD and BFAD.

6. BnBs with revoked SLTOs shall be blacklisted and shall not be entitled to future grants and license to operate. The DOH, through its CHDs, shall account for the name of the officers of such BnBs to preclude the establishment of BnBs with different names by the same persons. Also, to be accounted for in the records for blacklisting is the specific location of the said BnBs with revoked SLTO in order to impel and enjoin the beneficiary community thereat to exercise due diligence that will preclude the BnBs from being blacklisted.

## VII. PHARMACEUTICAL DISTRIBUTION NETWORK REGISTRATION GUIDELINES

### A. Documentary Requirements

The following documents are the minimum application requirements to accredit a PDN:

1. Application form for Registration (see Annex C);
2. BFAD license as distributor or supplier, carrying only generic drugs;
3. Certificate of Registration with the Securities and Exchange Commission (SEC), Cooperative Development Authority (CDA), Department of Labor and Employment (DOLE) that will ensure that the NGO has a legal personality and has officers who are responsible and accountable for its operations (Section 3.3.1, COA Circular #96-003 dated 27 February 1996);
4. List of personnel, corresponding position title and job description;
5. Organizational chart;
6. List of infrastructure, equipment and other assets that service existing accredited or licensed BnB outlets;
7. List of network of functional provincial PDNs and specific address, contact person and his/her contact number;
8. List of operational BnBs, specific address and contact person and his/her contact number as beneficiaries or partners per functional PDN;
9. List of target BnBs for licensing and expansion;
10. Manual of operations (Administrative, Financial and Supply Management);
11. Latest financial statement for at least three (3) years operations to ensure that it has stable

financial conditions and has proven experience in fund management (Section 3.3.2, COA Circular #96-003 dated 27 February 1996);

12. List of projects that it has previously undertaken to show its experience and expertise in implementing the project to be funded (Section 3.3.4, COA Circular #96-003 dated 27 February 1996); and

13. Sustainability Proposal, which should include the following information:

- a) Target No. of BnBs for future licensing;
- b) Annual sales target for existing no. of BnBs;
- c) Annual sales target for BnBs targeted to be licensed;
- d) Simple economic analysis forecast (Projected expenditures, and income); and
- e) Proposed requisition for the first delivery of OTCs and two (2) selected prescription drugs.

## B. Registration Process

1. An applicant PDN shall apply for registration with the PHARMA 50 PMU. A PDN Application Form (Annex C) shall be accomplished and submitted to the PHARMA 50 PMU Secretariat together with the required supporting documents for evaluation. Thereafter, the Secretariat shall submit the PDN documents to the BnB-TWG.

2. The BnB-TWG, created for the purpose of reviewing the registration of PDNs, and directly reporting under the PHARMA 50 PMU, after having reviewed and evaluated documents relative to the said application (including the sustainability proposal), shall notify said applicant with the result of their application/registration.

3. The Project Executive Officer of the PHARMA 50 PMU shall be the authorized DOH Official that will be issuing Registration Certificates to the PDNs upon recommendation of the BnB-TWG, by Authority of the Secretary of Health.

4. The BnB-TWG and the Distribution Component of the PHARMA 50 PMU shall prepare the corresponding MOA with the PDN, once the Registration Certificate is issued.

5. The MOA shall provide the specific provisions on the terms and conditions of business and regulatory relationship between the DOH and the PDN, and the specific entitlements the PDN will receive from the DOH including the steps and procedures that will be traversed in availing technical assistance packages.

6. The DOH and the PDN shall maintain copies of the said MOA.

## C. Application/Renewal Fees

1. The Applicant PDN will be required to pay a fee that shall be determined by the DOH for the

processing of its Registration.

2. The renewal of the PDN Registration Certificate shall likewise be subject to a fee that shall be determined by the DOH. The exact fees that must be paid shall be known and disseminated through Department Memoranda.

#### D. Validity of the PDN Registration Certificate and Renewal

1. The Registration Certificate shall have an initial validity period of one (1) year from the date of its issuance.

2. The Registration Certificate of the PDN shall be subject to yearly renewal thereof.

3. The Registration Certificate may be deemed renewed if there are no PHARMA 50 PMU, CHD and BFAD derogatory findings. Provided that, the PDN shall still be required to file the application for renewal.

#### E. Grounds for Revocation/Suspension of Registration and other Consequent Provisions

1. The grounds for revocation/suspension of Registration shall be based on, and similar to the conditions set for, the BnBs.

2. In addition to the conditions set as pertained by the preceding, the PDN's registration shall be suspended on the following occasions:

- a) Failure to comply with the submitted DOH approved Manual of Operations; and
- b) Ten percent (10%) of the BnBs under the PDN have become insolvent within a semester of operations reckoned on the first day of the Fiscal Year.

3. In addition to the conditions set as pertained in par. 1, the PDN's registration shall be revoked on the following occasions:

- a) The PDN declares insolvency/bankruptcy;
- b) Gross mismanagement;
- c) Thirty percent (30%) of the BnBs under the PDN have become insolvent within a semester of operations reckoned on the first day of the Fiscal Year; and
- d) The PDN fails to take necessary remedial or corrective measures within the prescribed measure derogatory findings as directed by BFAD or the CHD.

4. BnBs under a PDN with suspended or revoked registration may be operationally supervised by the CHDs until such time the PDN has gained its good standing registration status.

5. For every BnB, which SLTO is revoked, that has received grants and technical assistance from the DOH and are operationally under the PDN, the PDN shall be required to refund the equivalent

amount of drugs and technical assistance given to it by the DOH.

6. PDNs receiving technical assistance and grants from the DOH shall refund the equivalent amount given to it by DOH should its registration is revoked.

7. A PDN with revoked registration shall be considered as blacklisted (including its set of officers) and shall not be eligible to future grants and registration.

8. The name of the officers of the PDN with revoked registration shall be accounted for to preclude any attempts to create other PDNs with different names having the same officers.

## VIII. BnB SUPPLY MANAGEMENT OPERATIONS UNDER THE CENTERS FOR HEALTH DEVELOPMENT

### A. Handling Procedure for the initial deliveries of drugs procured through a Procurement Agent using funds from a Donor/Granting/Financing Institution

1. The initial deliveries of drugs procured through a Procurement Agent identified in a MOA using seed funds from Financing/Donor/Granting Institution, must have already undergone inspection and test sampling at the procurement agent's place, before delivery to the different CHDs.

2. The PHARMA 50 PMU shall monitor the results of the quality assurance inspection and testing done at procurement agent's site and shall promptly inform the CHDs of any incoming deliveries from the procurement agent, i.e. those that have passed the quality assurance protocols.

3. The CHDs shall be directly responsible in issuing the initial deliveries of the procurement agent to the different BnBs under its catchment area within three days from the receipt of CHD of the delivered goods. The CHDs will use Requisition and Issue Slip (RIS) in issuing drugs to the BnBs.

4. The duly signed original RIS indicating receipt of the drugs by the BnBs shall be collated by the CHDs and shall be submitted to the PHARMA 50 PMU.

5. The PHARMA 50 PMU shall collate the proofs of receipt by the BnBs forwarded by the CHDs and shall promptly submit these to the procurement agent for the purpose of liquidating the seed funds.

### B. Essential requirements to be imposed on BnBs

1. A Memorandum of Agreement (Annex B) for this purpose shall be jointly perfected by BnB operators, the proponent Local Government Unit (City/Municipality/Barangay), and the CHD concerned, to cover other operational and regulatory details.

2. An accountable person from the LGU/Barangay must be explicitly identified and shall be responsible for auditing the BnB to assure custodial fidelity of assets and properties.

3. The BnB and the proponent LGU must establish appropriate security measures in assuring the protection of BnBs assets.

4. The BnB operators shall be primarily responsible and accountable in the maintenance of the BnBs and the assets thereat, including sales.

#### C. Stocks Replenishments Orders and Emergency from the BnBs

1. The BnBs shall replenish their stocks by procuring from suppliers registered by the CHD with the approved CHD established drug prices.

2. The BnBs shall furnish the CHDs their request for replenishments by submitting a list of drugs that needs to be ordered, with the corresponding required quantities and a certificate that funds are available to cover such request. The request should be made quarterly with deadlines that shall be established by the CHD and signed by the BnB accountable officer/operator. The drugs to be ordered therefore should be good for at least one-quarter.

3. On sudden stock-outs, the BnB may re-order directly from the DOH/CHD Registered BnB drug supplier or through the CHD.

4. The CHD shall undertake a public bidding that will lead to the determination of registered suppliers for BnBs and the corresponding unit prices of the PHARMA 50 PMU approved BnB drugs, (i.e., acquisition cost from the CHD registered BnB supplier and the allowable BnB selling price) that will be applied by the BnBs. Furthermore, the CHD shall be authorized to request the PITC for price list of drugs and to request the latter to procure the essential drugs for the BnBs, whenever it is more advantageous to the Government.

5. The CHD shall be responsible for monitoring the deliveries made by the registered suppliers if such are covered with the appropriate Quality Assurance documents such as, Certificate of Product Registrations or Batch Certificates to the BnBs.

6. Only drugs reflected on the approved list of drugs to be dispensed specifically for BnBs as covered by the appropriate DOH issuance and have passed the BFAD Quality Assurance Protocol should be procured by BnBs, subject to the review and approval of the CHD.

7. BnBs may order for replenishment for sudden stock-outs and during emergencies such as in times of disaster and calamities notwithstanding the scheduled procurement cycles and deadlines set by the CHD at anytime during their operations subject to clearance from the DOH-CHD.

#### D. BnB Supplier Eligibility/Registration

1. The CHD, in coordination with the PHARMA 50 PMU, shall conduct BnB Supplier Eligibility/Registration processing at least once a year.

2. The CHD shall inform the PHARMA 50 PMU any change on the status and deviation of performance of the BnB suppliers.

3. Supplier Eligibility/Registration Requirements. The documents as listed in Annex D shall be required by the CHD from suppliers who wish to participate as CHD Registered BnB Suppliers.

#### E. BnB Drug Price Determination for Stock Replenishments

1. The CHD shall invite eligible/registered drug suppliers for BnBs at least twice a year to submit price offers for the PHARMA 50 PMU approve drug list within the framework of sealed public bidding or from PITC whichever is more advantageous to the Government.

2. The CHD, in coordination with the PHARMA 50 PMU, shall determine the lowest responsive bids and the results of which shall be forwarded to the BnBs.

3. The lowest responsive bidders shall be given Notice of Awards by the CHD, which will grant them authority to enter into Contract Agreements with the BnBs.

4. The submitted unit. price offers should have a validity of at least six (6) months.

5. The performance of drug suppliers of BnBs from participation in the public bidding until Contract Execution shall be monitored and any deviation of performance that will adversely affect the operations of the BnB shall be reflected as a derogatory remark that would result to downgrading or revocation of the drug suppliers registration/eligibility.

6. The CHD, in coordination with the PHARMA 50 PMU, shall promptly and regularly inform the BnBs of the list of authorized BnB drug suppliers and the corresponding approved acquisition price and selling price of the BnB drugs.

#### F. Fund Management Conditions for the BnBs

1. The BnB shall be authorized to earn income as a result of the PHARMA 50 PMU established mark-up that is added to the acquisition cost of drugs and medicines procured by PITC or through the CHDs unit price determination bidding process.

2. The sales proceeds (minus the mark-up for drugs) of BnBs shall be used solely for the purpose of re-ordering drugs and medicines and adjunct needs of the BnBs, subject to the conditions that may be set by their respective CHD Director that shall be embodied in the MOA for this specific activity.

3. To assure the sustainability of the BnBs, one-third (1/3) of the total profit shall serve as infusion fund (Le. it will be added to the amount of initial capital provided in case the BnB is recipient of a grant) for procurement of BnB drugs and medicines, and the rest of the profit shall be used as BnB



operating expenses and incidental expenses for BnB operators

4. The BnBs shall submit quarterly financial reports (within 15 days every end of each quarter) to the CHDs on the status of the implementation thereof. Such report should contain these basic information - sales, and stock inventory at the end of each quarter.

## IX. BnB MANAGEMENT OPERATIONS UNDER THE PHARMACEUTICAL DISTRIBUTION NETWORKS

### A. Administrative, Financial and Supply Management Process

1. The PDNs shall be required to present their Manual of Operations to the PHARMA 50 PMU reflecting therein the administrative, financial and supply management procedures and their reporting mechanisms showing data flow relationships with its BnBs.

2. The Manual of Operations must be approved by the Project Executive Officer, Pharma 50 PMU through the recommending approval of the BnB TWG and the Pharma 50 Operations Center.

### B. Handling Procedure for the initial deliveries of drugs procured through a Procurement Agent using funds from a Donor/ Granting/Financing Institution

1. The initial deliveries of drugs procured through a Procurement Agent identified in a MOA using seed funds from Financing/Donor/Granting Institution, must have already undergone inspection and test sampling at the procurement agent's place, before delivery to the PDN.

2. The PHARMA 50 PMU shall monitor the results of the quality assurance inspection and testing done at Procurement Agent's site and shall promptly inform the PDN of any incoming deliveries from the procurement agent, i.e., those that have passed the quality assurance protocols.

3. The PDN shall be directly responsible in issuing the initial deliveries of the Procurement Agent to the different BnBs under its catchment area within three (3) days from the receipt of CHD of the delivered goods. The PDN will use Requisition and Issue Slip (RIS) or the DOH-approved document in issuing drugs to the BnBs.

4. The duly signed original RIS indicating receipt of the drugs by the BnBs shall be collated by the PDN and shall be submitted to the PHARMA 50 PMU.

5. The PHARMA 50 PMU shall collate the BnB's proofs of receipt forwarded by the PDN and shall promptly submit these to the Procurement Agent for the purpose of liquidating the seed funds.

### C. Essential requirements to be imposed on BnBs

1. A Memorandum of Agreement similar to Annex B shall be jointly perfected by the PDN, the BnB operators under the PDN, the proponent LGU (City/Municipality/Barangay), and the CHD

concerned to cover other operational and regulatory details.

2. An accountable person from the LGU/Barangay must be explicitly identified and shall be responsible for auditing the BnB to assure custodial fidelity of assets and properties.
3. The BnB, the PDN, and the proponent LGU must establish appropriate security measures in assuring the protection of the assets of BnBs.
4. The BnB operators shall be primarily responsible and accountable on the maintenance of the BnB and the assets thereat, including sales.
5. The PDN shall be primarily responsible in assuring the sustainability of the BnB operations under it and compliance to regulatory requirements.

#### D. Stocks Replenishments Orders from the BnBs

1. The BnBs, through their PDNs, shall replenish their stocks by procuring from suppliers registered by the CHD/DOH with the approved CHD/DOH established drug prices.
2. The BnBs shall furnish the PDNs their request for replenishments by submitting a list of drugs that needs to be ordered, with the corresponding required quantities and a certificate that funds are available to cover such request. The request should be made quarterly with deadlines that shall be established by the PDN and signed by the BnB accountable officer/operator. The drugs to be ordered therefore should be good for at least one-quarter.
3. The PDN shall order drugs from a DOH/CHD registered BnB drug suppliers only.
4. On sudden stockouts, the BnB under the PDN may opt to order from the CHD itself or from DOH- CHD registered BnB drug supplier through their PDN.
5. In the absence of a DOH/CHD registered BnB drug supplier the PDN may undertake a procurement procedure which is similar or identical to public bidding that will lead to the determination of registered suppliers for BnBs and the corresponding unit prices for its BnB drugs, (i.e., acquisition cost from the registered BnB supplier and the allowable BnB selling price) that will be applied by the BnBs. However, the outcome of such procurement shall be elevated to the CHD or the DOH PMU 50 for price comparison before an award to the supplier is made by the PDN. Furthermore, the PDN shall be authorized to request the DOH, the CHD, and the PITC for price list of drugs and to request the latter to procure the essential drugs for the BnBs, whenever it is more advantageous. The name of the winning supplier, the item to be procured from said supplier the quantity and price should be elevated by the PDN to the DOH/CHD for formal authorization by the DOH/CHD.
6. The PDN shall be responsible for monitoring the deliveries made by the registered suppliers if such are covered with the appropriate Quality Assurance documents such as the Certificate of

Product Registrations or Batch Certificates to the BnBs under it.

7. Only drugs reflected on the approved list of drugs to be dispensed specifically for BnBs as covered by the appropriate DOH issuance and have passed the BFAD Quality Assurance Protocol should be procured by BnBs subject to the review and approval of the CHD.

#### E. BnB Drug Price Determination for Stock Replenishments by the PDN

1. The PDN may invite DOH/CHD eligible/registered drug suppliers for BnBs to submit price offers for the PHARMA 50 PMU-approved drug list within the framework of sealed public bidding or from PITC, whichever is more advantageous to it.

2. The PDN, in coordination with the PHARMA 50 PMU Unit and the CHD, shall determine the lowest responsive bids and the results of which shall be forwarded to the BnBs. The drug price shall be in no case be greater than that offered by BnBs directly under the CHDs.

3. The lowest responsive bidders shall be given Notice of Awards by the PDN, which will grant them authority to enter into Contract Agreements with the PDN and its BnB. The CHD shall be given a copy of said NOA.

4. The submitted unit price offers should have a validity of at least six (6) months.

5. The performance of drug suppliers of BnBs from participation in the public bidding until Contract Execution shall be monitored by the PDN and any deviation of performance that will adversely affect the operations of the BnB shall be reflected as a derogatory remark that would result to downgrading or revocation of the drug suppliers registration/eligibility and shall be reported to the CHD.

6. The PDN, in coordination with the CHD, and the PHARMA 50 PMU, shall promptly and regularly inform the BnBs the list of authorized BnB drug suppliers and the corresponding approved acquisition price and selling price of the BnB drugs.

#### F. Fund Management Conditions for the BnBs under the PDNs

1. The BnBs shall be authorized to earn income as a result of the PHARMA 50 PMU-established mark-up that is added to the acquisition cost of drugs and medicines directly procured by the PDN from DOH/CHD registered BnB suppliers or through the CHDs, and other authorized procurement agents using the unit price determination bidding process.

2. The sales proceeds (minus the mark-up for drugs) of the BnBs shall be used solely for the purpose of re-ordering drugs and medicines and adjunct needs of the BnBs, subject to the conditions that may be set by their respective CHD Director as shall be embodied in the MOA for this specific activity.

3. Sales proceeds of the BnBs minus the profit shall be remitted to the PDN who in turn shall send the check payable to DOH/CHD or to an authorized Procurement Agent (e.g. PITC) for subsequent re-stocking, copy furnished DOH Central Office Finance Service, the CHD and PHARMA 50 PMU.

4. The PDNs, shall submit quarterly financial reports (within 15 days every end of each quarter) to the CHDs on the status of the implementation of BnBs. Such report should contain these basic information - number of outlets, sales, stock inventory at the end of each quarter.

5. Repeat orders shall be served only after the PDN has remitted payment from previous orders, that is, the PDN has remitted 75% of the previous delivery to the authorized procurement agent.

#### X. RATIONAL DRUG USE AND QUALITY ASSURANCE

1. The BnBs shall be monitored by a supervising pharmacist, who shall at all times adhere to rational drug use practices in dispensing medicines.

2. The PDNs shall have the primary responsibility of procuring a supervising pharmacist for the BnBs under it. Nevertheless, it may ask assistance from the CHD/DOH and other stakeholders for said requirement.

3. The quantity of medicines to be dispensed by the BnBs shall be in accordance with the prescribed therapeutic regimens so as to preclude possible selling of OTC drugs in bulk to a single patient.

4. No BnB drugs shall find their way in the trade (e.g. wholesale and pilferage).

5. The drugs delivered to the BnBs may be subjected to DOH/BFAD post market surveillance protocols.

6. Expired drugs shall be reported to the nearest CHD and shall be disposed in accordance with the pertinent procedure that shall be prescribed by the DOH/CHD. A witness from DOH/CHD/BFAD shall be present whenever disposal of expired drugs is conducted.

7. The dispensing, storage and other conditions reflected on the label of the BnB drug products shall be adhered at all times.

#### XI. COORDINATING MECHANISMS BETWEEN THE CHDs AND THE PDNs RELATIVE TO THE OPTIMAL GEOGRAPHIC DISTRIBUTION OF BnBs

In order to enhance accessibility to cheaper and quality drugs, and to provide harmonization on existing frameworks that would lead to the optimum geOgraphic dispersal on the establishment of BnBs, the CHDs and the PDNs shall adhere to the following steps and specific conditions:

1. If there are existing BnBs in a province within the area of responsibility of the CHD which are operating under the auspices of the PDN, albeit not all barangays in the province are operationally covered by the PDN, and that same barangays with no BnBs are being earmarked by the CHD as prospective targets for BnB.

Guides to action:

a) The CHD shall make an inquiry to the PDN if it has intentions of setting-up BnBs to other barangays where there are no existing BnBs and if it can set-up BnBs on said locations within thirty (30) days;

b) Should the PDN fail to respond to the query within fifteen (15) working days, the CHD may set-up BnBs at its target areas where there are no existing BnBs even if such are within the area of the PDN;

c) Should the PDN indicate that it has no current capability to set-up BnBs within thirty (30) days, even if it has signified its intention, the CHD may set-up BnBs at its target areas with no existing BnBs; and

d) A report shall be submitted to the PHARMA 50 PMU relative to the status of its query and actions taken immediately when such occasion arises.

2. If there are no existing BnBs in a province within the area of responsibility of the CHD and under the auspices of the PDN.

Guides to action:

a) The CHD shall effect the setting-up of BnBs.

3. If there are existing BnBs in a province within the area of responsibility of the CHD which are operating under its auspices, albeit not all barangays in the province are operationally covered by the CHD, and that same barangays with no BnB are being earmarked by the PDN as prospective targets for BnBs.

Guides to action:

a) The PDN shall make an inquiry with the CHD if it has intentions of setting-up BnBs at the other barangays where there are no existing BnBs and if it can set-up BnBs at said locations within the next thirty (30) days.

b) Should the CHD fail to respond to the query within fifteen (15) working days, the PDN may set-up BnBs at its target areas where there are no existing BnBs.

c) Should the CHD indicate that it has no current capability to set-up BnBs within thirty (30) days, even if it has signified its intention, the NPF may set-up BnBs at its target areas where there are no

currently existing BnBs.

d) A report shall be submitted to the PHARMA 50 PMU relative to the status of its query and actions taken immediately when such occasion arises.

4. BnBs operating under the CHDs and the PDN may co-exist within the same province.

5. BnBs may be established regardless of their distance to the nearest existing regular pharmacy. However, the price of the drugs of the said BnB should at least be 20% lower than the generically equivalent drugs offered by the said nearest pharmacy.

## XII. PRIMARY RESPONSIBILITIES OF RECIPIENTS OF BnBs

The duly recognized organization or cooperative in charge of the BnB has the following responsibilities and accountabilities:

1. Adheres to Generics Law, Pharmacy Law, Bureau of Food and Drugs and other related laws;
2. Ensures project implementation in accordance with the guidelines stipulated in the BnB Operating Manual;
3. Keeps and maintains separate accounts and subsidiary records for assistance received;
4. Submits financial and physical status reports to entities which are sources of funds;
5. Ensures that the community or their members be regularly informed of their financial and physical status;
6. Educates the community on the principle of rational drug use; and

## XIII. PRIMARY RESPONSIBILITIES OF THE PHARMACEUTICAL DISTRIBUTION NETWORK

1. Oversee and manage the operations of the PDN and its network of BnBs in accordance with its DOH approved Manual of Operations;
2. Validate pertinent documents furnished by procurement agents and to coordinate with its network of BnBs incoming deliveries of OTCs and two (2) selected prescription drugs received from the Procurement Agent or a DOH/CHD registered BnB drug supplier, as approved by the Project EExecutive Officer of PMARMA 50 PMU.
3. Ensure the delivery of the same to licensed and/or registered BnBs, and that these BnBs sell these drugs following the DOH/CHD prescribed selling price and licensing standards.

4. Account for and record the movement of the stocks and the revenue generated from the sales at its level and from each provincial PDN and its recipient BnBs.
5. Submit financial status and accomplishments reports, monthly, provide inventory and financial status including fund liquidation to the Project Executive Officer of PHARMA 50 PMU and CHD concerned.
6. Coordinate with the DOH through the PHARMA 50 PMU and the CHD and local government officials in the planning design and implementing project activities.

#### XIV. PROJECT MONITORING

1. CHDs and PHARMA 50 PMU shall be the lead units in monitoring the performance of all BnBs and PDNs, notwithstanding and without prejudice to a similar role that the LGU proponent may undertake.
2. The CHDs and PHARMA 50 PMU shall have the authority to check on the records of all the BnBs (including those under PDNs) and the PDNs at any given time, notwithstanding and without prejudice to the regulatory functions of BFAD.
3. BnBs, including those under PDNs, and the PDNs themselves must maintain the integrity and transparency of their records and shall be made available whenever asked by the CHD concerned, the PHARMA 50 PMU and other regulatory units.
4. Monitoring reports shall be periodically submitted by the CHDs to the Project Executive Officer PHARMA 50 PMU every quarter or as often as practicable. The routine reports of the PDNs must first be forwarded to the CHDs.

#### XV. COORDINATING INSTRUCTIONS

1. The CHD Director shall have the over-all responsibility on the implementation of the system and shall be supported by the DOH Central Office Staff, particularly the PHARMA 50 PMU, by determining estimates and recommendations for improvement in the operation of the target BnBs with the assurance that provisions of the guidelines will be adhered to.
2. Policy issues shall be referred to the Office of Project Executive Officer, PHARMA 50 PMU, for final clearance and approval.
3. The BFAD Director shall assist the CHDs and the PHARMA 50 PMU by detailing Food and Drug Regulations Officers (FDROs) or by providing technical assistance and experts opinion as may be required in establishing the BnBs and monitoring BnB performance.
4. The Chiefs of Hospitals of Government Owned and Controlled Hospitals and the CHD Directors (if there are available pharmacists at the CHDs) may authorize their pharmacists, depending on

their relative availability, to serve as supervising pharmacists of the BnBs and may conduct inspection on official time.

5. The LGUs, being responsible for the health needs of their constituents, shall be encouraged to perform the following acts, which shall likewise be embodied in a MOA between the LGU, the CHD and the BnB:

- a) Assist in providing space for BnB stores;
- b) Assist in providing pharmacist-supervisors for BnB outlets; and
- c) Provide grant funds for the establishment of BnBs.

#### XVI. REPEALING CLAUSE

Administrative Order No. 23-A., dated 05 July 1996; Administrative Order No. 70, dated 03 January 2002; Administrative Order No. 159 dated 07 October 2002; Administrative Order No. 64 dated 01 July 2003; Department Memorandum No. 2 dated January 14, 2004; and Department Memorandum No. 4 dated January 16, 2004, are hereby superseded by this Order. All other administrative issuances with provisions that are inconsistent with the provisions of this Order are hereby amended, modified, repealed and/or revoked accordingly.

#### XVII. SEPARABILITY CLAUSE

If any provision in these Guidelines, or application of such provision to any circumstance, is held invalid, the remainder of these Guidelines shall not be affected thereby.

#### XVIII. EFFECTIVITY

This Order shall take effect immediately.

**MANUEL M. DAYRIT, M.D., MSc.**  
Secretary of Health





