



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
San Lazaro Compound, Rizal Avenue
Sta. Cruz, Manila, Philippines
Tel. No. 711-9502/711-9503



03 January 2002

ADMINISTRATIVE ORDER

No. 70 s. 2002

SUBJECT: Licensing of Botika ng Barangays (BnB) in various Local Government Units

Pursuant to section 26 (a) of RA 3720 known as the Foods, Drugs, Devices and Cosmetics Act as amended, RA 6675 known as the Generics Act of 1988 and in response to the clarion call of the President of the Philippines in her State of the Nation Address to reduce the cost of medicine by 50%, the following guidelines are hereby promulgated for the Issuance of a Botika ng Barangay License to Operate (BnB LTO).

I. OBJECTIVE

This order is issued to set the rules and regulations for the licensing of Botika ng Barangay with the end goal of ensuring access to low priced good quality medicines by the Filipinos particularly the marginalized sector of the population.

II. DEFINITION OF TERMS

- Botika ng Barangay (BnB) – refers to a drug outlet wherein primary, non-prescription generic drugs listed in the Philippine National Drug Formulary (PNDF) and selected prescription drugs (co-trimoxazole and amoxicillin) are sold/made available.
- 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. The BnB operator will be trained and have to be accredited by the DOH to serve far flung barangays and designated depressed areas.
- Community Organization (CO) or Non-Government Organization (NGO) – refers to community organization that sponsors the establishment of a Botika ng Barangay (BnB) that is registered either as a cooperative with the Cooperative Development Authority (CDA); or a foundation/association registered with the SEC, or a worker's association registered with DOLE or any form of organization

Signed AD
Received in the Records
Section on 3-12-02

that is authorized and certified by duly authorized agency. It is represented by a set of officers who do not personally profit from the operations of the BnB.

- Local Government Units – refers to the territorial and political subdivision of the State.
- Memorandum of Agreement (MOA) -- refers to the agreement in partnership between and among the non-government and non-profit organizations; the community outlets and the local government units where they join resources to put together a botika ng barangay with the objective of helping the poor people.
- Supervising Pharmacist – refers to a licensed pharmacist who shall be responsible for the quality standards in the operation of the BnB. He/she maybe a private pharmacist directly hired by the BnB or by the LGU, CO or NGO or a government pharmacist employed in the nearest government hospital designated to oversee/supervise the BnB.

III. LICENSING PROCEDURE

A. Requirements

The following documents are requirements for the licensing of BnB:
(See Annex A)

1. Notarized Petition Form (See Annex B)

The form can be secured from the Licensing section of the Regulation Division I (Bureau of Food and Drug (BFAD) Alabang, Muntinlupa) or Registration, Licensing and Enforcement Division (RLED) of the nearest Center for Health Development (CHD)

Petition forms shall include the following:

- a. Name, address, residence certificate number, Professional Regulation Commission (PRC) no. of the supervising pharmacist whether private or public practitioner.
- b. Registered name and address of the sponsoring organization and the type of organization, if applicable
- c. Name, address, residence certificate of the representative of the community organization that owns the BnB.
- d. Business hours of the BnB
- e. Name of barangays in the municipality within the area of coverage by the BnB.
- f. Initial source of capital funds and the amount of capital invested

- g. Signatories of representative of community organization and of supervising pharmacist
- h. Tentative list of drug products to be carried by the BnB
- i. Source of the products

2. Notarized Joint Affidavit of Undertaking (See Annex C)

This form can be secured from the licensing section of the Regulation Division I (BFAD Alabang , Muntinlupa) or RLED of the nearest CHD.

Joint Affidavit of Undertakings shall include the following:

- a. Name, address, PRC No. of supervising pharmacist
- b. Name, address of community organization representative
- c. Name, address of at least one BnB operator
- d. Conditions that stipulate the following:
 - Supervision shall be under a registered pharmacist or as an alternative a government hospital pharmacist with a written commitment to oversee supervise BnB
 - Display the duly approved License to Operate within the BnB
 - Notify Metro Manila BFAD or RLED of CHD in case of any change in the circumstances such as transfer of location, change of supervising pharmacist , BnB operator or ownership of BnB

3. Proof of Support Agreement

This form can be secured from the LGU and /or CO/NGO that supervises the implementation of the BnB

Proof of support will come in the form of Memorandum of Agreement (MOA) Social Franchising Agreements, and other forms of contracts that show that the BnB is supported by the local government units and/or non-government organization to ensure that it can provide good quality generic drugs at affordable prices.

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

The certificate of participation /attendance to a training shall be issued by DOH supported/accredited programs.

5. Contract of Lease/Use of privately or government owned building

This is an authority to be issued by the owner or his duly authorized personnel to the applicant regarding his right to use a space within a definite period of time.

6. Location/Vicinity Map of the BnB

Map shall show the location of the BnB and the distance of BnB from existing drugstore(s) in the area.

7. Floor plan

8. List of supplier (name and address) and list of products (in Generics) to be sold in the BnB and the suggested selling price (SRP)

9. Copy of picture of the drugstore bearing the signboard

This shall show that the correct business name of the BnB is the same as the one on the signboard.

B. Procedural Guidelines

The concerned organizations and the different units in the DOH shall adhere to these guidelines :

1. A BnB shall submit all the necessary documents to the DOH representative (DOH Rep) in the municipality where the BnB is located .The DOH Rep shall authenticate and process all information .He/She shall ensure the completeness of all the documents. He/she shall likewise schedule on-site inspection.

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

- a. Premises/Location Site

1. A wooden or plastic signboard bearing the registered name that shall be placed in the front of the BnB outlet.
2. A suitable, well ventilated area with concrete or wooden flooring

3. A suitable and proper place for adequate storage of drug products.

b. Record Book

1. 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, ate of purchase, name of patient
2. Sales record book for OTC products

c. Reference Materials and Documents

1. RA 5921, RA 3720, RA 6675, RA 8203, AO 23 s. 1996 and the revised Administrative Order for BnB)
2. Philippine National Drug Formulary (PNDF) latest edition

d. Other Requirements

1. BnB seal (rubber stamp) and stamp pad. Such seal must bear the name and address of the BnB, date when drug was dispensed, names of product (generic) potency, quantity dispensed, lot number and expiry date, signature of the dispenser
 2. 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
 3. File of prescription to be kept oft two (2) years subject to BFAD inspection.
 4. A full time BnB operator, physically present while the BnB is open for business
2. Once completed, DOH Rep shall submit all the documents and report to provincial Food and Drug Regulatory Officer (FDRO). The FDRO shall check all the submitted document and shall ensure that the lists of drugs are only those that are in the "allowed formulary "for BnBs. FDROs shall also check whether the supplier of the BnB is a licensed distributor for BnB and is accredited with the Project Management Unit (PMU) Pharma 50 for BnBs. If not accredited, FDRO shall advise the BnB to look for another accredited Pharmaceutical Distribution Network (PDN). Once all these are in order, the provincial FDRO shall collect from the BnB the licensing fee.

3. After determining compliance to all requirements per submitted documents and as established during inspection, the provincial FDROs shall forward all applications to the Center for Health Development attn.: Local Health Assistance Division (CHD LHAD). CHD LHAD shall keep a list of applicants for future follow-up and monitoring.
4. The CHD LHAD shall submit all applications to the Technical Working Group (TWG) for BnB in the PMU Pharma 50 project for endorsement to BFAD Regulation 1 Division for appropriate licensing.
5. As soon as the BFAD Regulation 1 Division issues a license to operate to the BnB, the license shall be released through the TWG for BnB of the PMU Pharma 50 copy furnished CHD LHAD for updating their listing of BnB. .
6. The final license to operate shall be released by the provincial FDRO through the DOH Rep to the BnB who applied.

IV. SCHEDULE OF FEES

An initial payment of Two Hundred Pesos (P200.00) shall be collected from the applicant BnB before a BnB License to Operate will be processed/issued.

V. VALIDITY OF THE BnB LTO

Initial validity period of one year from date of issue subject to yearly renewal.

VI. RENEWAL OF BnB LICENSE TO OPERATE

BnB must have a history of satisfactory compliance with BnB rules and regulations. Renewal of the license to operate is also subject to favorable

endorsement of the BLHD.


A copy of application for renewal of BnB License to Operate accomplished by the BnB authorized represented must be submitted.

VII. GROUNDS FOR REVOCATION/SUSPENSION OF BnB-LTO

1. Suspension of BnB License to Operate if and when it
 - 1.1. Fails to produce invoices and vouchers indicating lot numbers, expiry dates for drugs purchased.
 - 1.2. Refuses to allow entry of BFAD inspector
 - 1.3. Failure to inform BFAD of the changes in the circumstances of business, such but not limited to the change of pharmacist, etc. .
 - 1.4. Increase in the price of drug products by more than 100% from the preceding month.
 - 1.5. Other reasonable grounds as shall be detained by BFAD
2. Revocation of BnB LTO if any when it
 - 2.1. Sells or offers for sale adulterated, misbranded, substandard, counterfoil drugs, unregistered, expired and/or unsafe drugs or products marked "not for sale".
 - 2.2. Fails to take necessary remedial or corrective measures within the prescribed period as directed by BFAD.
 - 2.3. Other reasonable grounds as shall be determined by BFAD

IX. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days after publication in a newspaper of general circulation


MANUEL M. DAYRIT, MD, MSc.
Secretary of Health

CHECKLIST OF REQUIREMENTS FOR BOTIKA NG BARANGAY (BnB)**I. DOCUMENTARY :**

- 4 Notarized Petition Form /Joint Affidavit of Undertaking
- 4 Memorandum of Agreement (MOA) with Local Government Unit (LGU) and NGO that offers support for the establishment and quality control of the BnB
- 4 Pharmacist Board Certificate, valid PRC-ID picture or as alternative a written commitment to supervise/oversee BnB operation by an accredited registered government hospital pharmacist/ PPhA Chapter Pharmacist that specify days and time of personal/physical presence in the BnB
- 4 Proof of registration by official government body of the community organization which petitions for the establishment of a BnB
- 4 Certificate of training of BnB Operator or Pharmacy Clerk/BHW/Community Volunteer Health Worker issued by CHD/Metro Manila BFAD accredited DOH Program/Project or NGO.
- 4 Location /Vicinity Map-include specific landmarks for accessibility to place
- 4 Floor plan-no specific area required
- 4 List of products to be sold (generic drugs only) and drugs of the DOH programs must be approved by a DOH Accrediting Committee

II. SPECIFICATION REQUIREMENTS – to be made available during inspection

- 4 Reference Materials (RA 5921,3720,6675,8203, AO 23 s. 1996)
- 4 Formulary consist of generic drugs in Primary Medical Care drugs either for doctorless facilities or with doctors but satisfying with DOH Program accreditation requirements.
- 4 Prescription Book (for prescription drugs)
- 4 Prescription filed for 2 years
- 4 Outlet Transaction Form (Sales Record Book)
- 4 Rubber stamp of BnB outlet
- 4 Sign Board

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City, Alabang, Muntinlupa City
CHD _____(address)

PETITION FORM

Comes now the undersigned, petitioner unto the Bureau of Food and Drugs Department of Health, Alabang Muntinlupa City/ CHD _____(address) , respectfully alleges:

First: That the petitioner is a duly registered non-government organization under Philippine laws and is duly represented by _____ its President;

Second: That the petitioner desires to open a Botika ng Barangay outlet located at _____ and shall be known as _____;

Third That the said BnB shall be opened for business from _____ AM to _____ PM and shall be under the supervision of _____, a duly registered pharmacist with Certificate of Registration PRC No. _____ issued on _____ at _____

Fourth: That _____ is the trained operator of the said BnB with postal address at _____

Fifth: That the amount of capital invested for the said BnB is Php _____ as sourced from _____

Sixth: That the petitioner hereby agrees to change the business name of the said BnB in the event that there is a similar or same name registered with the Bureau of Food and Drugs/CHD No. _____ or if rules later that it is misleading.

Wherefore, the petitioner respectfully prays that he/she be granted a Special License to Operate a Botika ng Barangay outlet after inspection thereof and after compliance with the requirements. Bureau of Food and Drugs, DOH, M.M./CHD No. _____ (address)

The undersigned, as manager/proponent of the BnB hereby declares under oath that he/she conforms to the declaration

_____ of the petitioner

BnB Manager/Proponent _____
Address: _____
Res. Cert. No. _____
Issued on _____ at _____
Tel. No. _____

Respectfully submitted

Printed Name/Signature of Pharmacist

Res. Cert. No. _____
Issued on _____ at _____
Tel. No. _____

JOINT AFFIDAVIT OF UNDERTAKING

Pharmacist in Charge

With PRC No. _____ issued on _____ of legal age,
Single /Married, and a resident of _____
after having been sworn in accordance with law, hereby declare:

- 1) That we are fully aware of the provisions of Pharmacy Law, the Foods, Drugs, Devices and Cosmetics Act, the Generic Act of 1988, the Special Law on Counterfeit AO 23 s. 1996 otherwise known as Guidelines on the Development and Establishment of Botika ng Barangay.
- 2) That the operation of BnB shall be from _____ AM to _____ PM
under the immediate supervision of pharmacist or ;

as an alternative a government pharmacist of nearest government hospital, _____
located at _____ hereby
commits responsibility in the supervision/oversee of the BnB operation, the physical presence being on
_____ from _____ AM to
_____ PM
- 3) That the BnB shall display its approved **SLTO** in a conspicuous place of the BnB outlet;
- 4) That we shall notify CHD/MM BFAD in case of any change in the circumstances of our application for a **Special License to Operate**, including but not limited to change of location, registration or change of pharmacist.

Witness whereof, we hereunto affix our signature this _____ day of _____
20_____.

Manager/Proponent

Pharmacist in Charge

Res. Cert. No. _____
Issued on _____
At _____

Res. Cert. _____
Issued on _____
At _____

SUBSCRIBE AND SWORN TO ME THIS _____ day of _____ 20_____ at

NOTARY PUBLIC
Until December 31, 20_____