



Republic of the Philippines
Department of Health

OFFICE OF THE SECRETARY

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04 April 2005

ADMINISTRATIVE ORDER

No. 2005-0011

SUBJECT : Supplemental Guidelines to Administrative Order No. 144 series 2004, entitled: "Guidelines for the Establishment and Operations of Botikang Barangays (BnB) and Pharmaceutical Distribution (PDNs)" relative to the inclusion of other drugs which are classified as Prescription Drugs and other related matters

I. Rationale

The Department of Health's year 2000 mortality statistics reveal that the current major causes of death in the country today, in order of decreasing prevalence, are: diseases of the heart, diseases of the vascular system, malignant neoplasm, pneumonia, accidents, tuberculosis, chronic obstructive pulmonary diseases, certain conditions originating in the perinatal period, diabetes mellitus, and nephritis / nephrosis. Year 2001 Morbidity data, on the other hand, reveals that the ten leading causes of illnesses, in decreasing order, are: diarrheas, bronchitis, pneumonia, influenza, hypertension, tuberculosis, diseases of the heart, malaria, measles and chickenpox.

It is noteworthy that still, majority of the diseases listed above are highly preventable given the proper access to and the availability of health services and pharmaceutical products. Prominent among the preventable mortality and morbidity diseases listed above include those related to diseases of the heart and the vascular system, pneumonias, chronic obstructive pulmonary diseases, and diabetes mellitus and its related complications. Furthermore, these diseases require lifetime medications and more commonly afflicts the senior citizens.

With the passage of the Expanded Senior Citizen's Act, it is now mandated that senior citizens be granted 20% discount on all medications. This has been the subject of numerous debates between senior citizen's group and the retail drugstores.

The 2001 mandate given by Her Excellency, President Gloria Macapagal Arroyo to the Department of Health is to cut by half the prices of medicines commonly bought by the poor. As such, the Department has done through various initiatives, like the Botikang Barangay (BnB), wherein low cost high quality drugs and medicines are made available to poor communities and to places where there is no access to these kinds of medicines.

Therefore, with the prevalence of the abovementioned diseases which are highly preventable given the proper lifestyle modifications and access to pharmaceuticals, the issue regarding the access to these chronic medications, especially of the senior citizen's group and the mandate given to the Department of Health, the list of the BnB drugs that are allowed to be sold per Department Memorandum No. 31 series 2001 was recommended to be amended to

include the following:

- Metformin 500 mg tablet
- Glibenclamide 5 mg tablet
- Metoprolol 50 mg tablet
- Captopril 25 mg tablet
- Salbutamol 2 mg tablet
- Salbutamol 2 mg/ 5 ml syrup (60mL)

Albeit, such recommendation as supported by the National Formulary Committee as shown in Annex A (NFC letter dated 17 February 2005) and by the Bureau of Food and Drugs as shown in Annex B (BFAD letter dated 03 March 2005) should be subject to specific guidelines that will assure rational drug use and accountability.

II. Objective

This Order is formulated in order to:

1. Provide an institutional mechanism for the inclusion of drugs in the BnB drug list;
2. Provide a safety net for dispensing of BnB drugs, which are considered as prescription drugs; and
3. Provide a clear policy statement and procedure for LGUs who wish to operate BnBs by themselves.

III. Scope and Applicability

This Order shall be applicable to all Botika ng Barangays which existence are covered by Administrative Order No. 144 s. 2004 and shall serve as a regulatory basis that will guide the Bureau of Food and Drugs, the Centers for Health Development, the Pharmaceutical Management Unit of the Department of Health and other concerned Agencies and entities.

IV. General Guidelines

1. The Department of Health authorizes the dispensing of the following essential drugs to the Botika ng Barangay subject to the strict implementation of the dispensing guidelines as reflected hereon:

- a) Metformin 500 mg tablet
- b) Glibenclamide 5 mg tablet
- c) Metoprolol 50 mg tablet
- d) Captopril 25 mg tablet
- e) Salbutamol 2 mg tablet
- f) Salbutamol 2 mg/ 5 ml syrup (60mL)

2. The Food and Drug Regulatory Officers (FDROs) assigned at each Centers for Health Development (CHDs), under the immediate supervision of the CHD Directors and under the regulatory supervision of the Director of the Bureau of Food and Drugs (BFAD) shall be responsible for the strict monitoring of the dispensing protocols in this Order and shall include such activities under their regular work and financial and operational plans.

3. The Centers for Health Development, particularly the unit so assigned to handle the low cost quality medicines program shall assure the training of Botika ng Barangay operators under their jurisdiction and shall include in their work and financial, and operational plans such training requirement in collaboration with BFAD FDROs in the CHDs. This means that such activities will be considered as routine activities for planning and implementation.

V. Guidelines for Inclusion of Drugs for BnB Use

1. All drugs that are to be included in the Botika ng Barangay drug list shall be jointly and properly reviewed by the Pharmaceutical Management Unit (Pharma 50 Unit) of the Department of Health, the Bureau of Food and Drugs (BFAD) and the National Formulary Committee (NFC). The joint recommendations of the three (3) aforementioned units shall be forwarded to the Secretary of Health and this shall include the list of drugs that are to be adopted in the BnB drug list along with specific annotations and/or rationale why such drugs were recommended.

2. Requests for drugs to be included in the BnB drug list that are recommended by the Centers for Health Development or other stakeholders must all pass through the Pharma 50 Unit. The Pharma 50 Unit shall within reasonable time collect such requests and shall forward the same to the BFAD and NFC.

3. The recommended drugs for inclusion in the BnB drug list shall be approved by the Secretary of Health and shall be released for dissemination through a Department Memorandum. The rationale for the inclusion of such drugs shall be appended as annex(es) of the Department Memorandum. An exception to such, are the subject drugs as mentioned in the rationale of this Order who are approved hereon by the Secretary of Health using this issuance instrument and are added to the BnB drug list mentioned in the Department Memorandum 31 series of 2001, subject to the dispensing guidelines reflected below.

VI. Dispensing Guidelines

1. The Botika ng Barangay shall be allowed to sell prescription drugs and medicines subject to the specific approval of the Department of Health and safety nets and guidelines that will assure rational drug use and accountability.

2. At all times, only the supervising pharmacist alone has the authority to dispense the six prescription drugs and medicines as stated in Item IV (1). The basis of such dispensing shall be a prescription duly signed and issued by a physician.

3. Under no circumstances shall prescription drug substitution be allowed. In cases that another drug is preferred, the patient must return to his primary care physician and secure another prescription.

4. The supervising pharmacist and the BnB operator shall jointly keep a separate record containing the names of patients, their primary care physician, the diagnosis of the patient, and the volume of medicines dispensed.

5. The BnB operator and/or the dispensing pharmacist shall advise the patients/consumers to report any adverse reactions or any anomalous effect observed as a suspected consequence on the use of procured medicines. Once such reports are made, the BnB operator, jointly with the supervising pharmacist shall record the name of the patient, the drugs taken, the adverse effects reported, the date of the incident in a logbook and shall accordingly forward the same

information to the CHD Director and the Director of the BFAD.

6. The volume of medicines to be dispensed per patient shall be computed to amount to a maximum of one (1) month supply only.

7. If, based on the records, a client buys more than what is allowable based on proper prescription / dosage vis-à-vis volume dispensed, sale shall be withheld to the client pending investigation of the supervising pharmacist, who shall submit the report to the BnB Coordinator of the CHD concerned for proper action.

8. To maximize the time spent by the supervising pharmacist, the BnB operator can, beforehand, prepare the volume to be dispensed.

9. After twelve (12) months of sale to a client (computed from the first purchase to the current purchase) and every twelve months thereafter, a written note from the physician, stating that patient follow-up was made, must be presented in order for sale to the client to be continued.

10. The BnB operators shall only be allowed to sell the above-mentioned drugs and medicines after they have successfully undergone a technical training course that is to be conducted by the Department of Health and in the physical presence of a dispensing pharmacist in accordance to item VI (2) of this order.

VII. Separability Clause

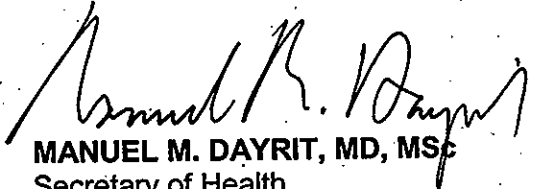
If any part, term or provision of this Order shall be declared invalid or unenforceable, the validity or the enforceability of the remaining parts or provisions shall not be affected, and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

VIII. Repealing Clause

Previous Orders and similar issuances which specific provisions are inconsistent with those provided hereon are deemed repealed and modified accordingly.

IX. Effectivity

This Order shall take effect immediately.


MANUEL M. DAYRIT, MD, MSc
Secretary of Health



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17 February 2005

ANNEX A

DAVID J. LOZADA, JR., M.D.
Assistant Secretary of Health
Project Executive Officer
PHARMA 50- OPCEN

Dear Dr. Lozada:

This has reference to your letter dated 7 February 2005 regarding the inclusion of the following prescription drugs in the Botikang Barangay drug list:

1. Metformin 500 mg tablet (oral hypoglycemic)
2. Glibenclamide 5 mg tablet (oral hypoglycemic)
3. Metoprolol 50 mg tablet (antihypertensive)
4. Captopril 25 mg tablet (antihypertensive)
5. Salbutamol 2 mg tablet and 2 mg/5 mL syrup (asthmatic)

Please be informed that captopril and salbutamol have been included in the earlier editions of PNDF, Volume I and are retained in the current formulary under the list of Primary Medical Care Drugs. Moreover, upon evaluation of the National Formulary Committee, the first three mentioned drugs (metformin, glibenclamide and metoprolol) are considered to be included under the same list in addition to the Primary Medical Care Drugs for all rural health units (RHUs) of the PNDF, Volume I on its 6th edition.

The committee allows the inclusion of the aforementioned drugs provided that the following procedure shall be observed:


1. A prescription for the drug shall be presented to the pharmacist prior to dispensing of the above medicines.
2. The pharmacist supervising the BnB outlet shall be the one to dispense the medicines pursuant to Administrative Order No. 144 series of 2004 which states that dispensing of prescription medicines must be handled by the pharmacist who shall supervise a BnB outlet twice a month with two (2) hours per visit. Moreover, a BnB operator can be trained by the assigned pharmacist to dispense these prescription drugs.
3. The said drugs can be dispensed as maintenance medicines as refill of a prescription previously issued by a physician. This means that the patient has consulted his physician before he purchases his medication from a BnB outlet.

We hope this would clarify the matter.

Thank you.

Very truly yours,

For the National Formulary Committee


ESTRELLA PAJE-VILLAR, M.D.
Chairperson

c.c. Bureau of Food and Drugs



3 March 2005

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
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MAKAYA AT MALUSOG
HA FAMAHAN

ANNEX B

DAVID J. LOZADA JR. MD,MPA,CESO III
Assistant Secretary of Health
Project Executive Officer
Pharma 50-Department of Health

Subject: Inclusion of additional five (5) prescription drugs in the Botika ng Barangay Drug List.

Dear Dr. Lozada,

Greetings!

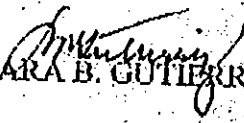
This is with regard to the request for the inclusion of additional five (5) prescription drugs to the lists of drugs that can be distributed by the Botika ng Barangay.

Based on Administrative Order No. 144 s.2004 only two(2) antibiotics namely, Co-trimoxazole and Amoxicillin are allowed. Since the five (5) additional prescription drugs proposed to be included in the BNB drug list are not antibiotics, it is our considered opinion that the proposed five additional prescription drugs cannot be included in the BNBs drug list, unless the aforesaid A.O. is amended.

Furthermore, Republic Act 5921 (Pharmacy Law) provides that dispensing of medicines be done only by a registered pharmacist.

We appreciate your continued cooperation and coordination regarding this matter.

Very truly yours,


Prof. LETICIA BARBARA B. GUTIERREZ, M.S.
Director

"Smoking is Dangerous to your Health"