

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

Administrative Order No. 2012 - 00 30 DEC 2 0 2012

### Subject: <u>Guidelines on Foreign Surgical and Medical Mission Program in Support</u> of Universal Health Care/ Kalusugan Pangkalahatan

#### I. RATIONALE

Foreign Surgical and Medical Missions (FSMMs) in the Philippines are activities where medical interventions and/or surgical services are provided to selected underserved areas and communities by a foreign individual or an organization in partnership with a local partner, usually a local government unit, non-government organization, hospital or medical society. These missions also serve as a means of professional advancement and venue by which foreign medical practitioners can share their talents and expertise for the purpose of continuing medical education.

FSMMs play an important role in the delivery of health care services, especially in attaining the Universal Health Care (UHC) or Kalusugan Pangkalahatan (KP). UHC/KP is the Aquino administration's health agenda to ensure that all Filipinos, beginning with the poor, are 1) able to access a reasonable level of health services at minimal cost, by being enrolled in the National Health Insurance Program; 2) cared for in modern health care facilities; and 3) prevented from falling ill by using public health services to improve health outcomes and attain health-related Millennium Development Goals (MDGs). It is being vigorously pursued through three strategic thrusts 1) financial risk protection by expanding the National health Insurance Program, 2) improving access to quality health services, and 3) scaling up MDGs.

Record shows that for years there have been numbers of FSMMs conducted nationwide. These FSMMs are facilitated by the Department of Health through the Bureau of International Health Cooperation (BIHC) and the Commission on Filipinos Overseas (CFO), in collaboration with the Professional Regulation Commission and the Department of Interior and Local Government. FSMMs are undertaken in the form of medical, surgical and dental missions or a combination of both medical and surgical or medical and dental missions. There are also some specialized missions conducted like cataract/eye care and cleft palate missions. Most of these are implemented on a one-time mode of short duration.

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In 2011 alone, 154 missions of varying nature were facilitated by the DOH and the CFO. Most of these were conducted in different parts of the country like the National Capital Region, Cebu, Bataan, Southern Leyte, Batangas, Nueva Ecija, Pangasinan, Abra, Quezon, and Sorsogon.

In the implementation of FSMMs, some challenges have been noted. One of the challenges is the proper identification of deserving areas where these missions' services are most wanted. There are also concerns on the targeting of beneficiaries, lack of structured programs for sustainability and continuity of care especially for the pre and post mission activities. More importantly, there is a need to enhance procedures and processes for faster and more efficient facilitation and coordination of the FSMMs.

It is in this view that the current FSMM implementation is being revisited.

#### **II. OBJECTIVE**

The guidelines shall stipulate the key principles, policies, and processes to rationalize FSMMs in the country and ensure that all FSMMs shall contribute to betterment of health services among Filipinos.

Particularly, this set of guidelines shall:

- 1. Institutionalize a sustainable system for an effective facilitation and coordination of all the FSMMs.
- 2. Provide guidance to all partners and stakeholders to converge and complement efforts towards a more enhanced and more comprehensive local health system development.

### **III. GUIDING PRINCIPLES**

- 1. FSMMs shall be aligned with the existing health strategies / programs under the UHC/Kalusugan Pangkalahatan.
- 2. Underserved communities shall be prioritized and a system for identifying the target beneficiaries shall be put in place.
- 3. Linkages and networks with all the stakeholders involved in FSMM shall be established.
- 4. All medical and surgical services shall be provided at no cost to the beneficiaries, however reimbursements shall be maximized under the National Health Insurance Program for all other related medicines / medical supplies and services provided through the local facilities and health service providers.
- 5. Only qualified and competent medical and other allied health workers shall perform the appropriate medical and surgical procedures.

## IV. THE FSMM PROGRAM

FSMM shall be implemented as a means of attaining and ensuring a more accessible, quality and appropriate health services for the poor. It shall complement rather than duplicate the existing health programs of the government. The successful implementation of FSMM needs the cooperation and collaboration of different stakeholders.

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The DOH, through the BIHC shall be the over-all in charge of coordinating the implementation of FSMMs. A FSMM Unit, under the BIHC shall be created which shall serve as the one stop shop for all FSMM concerns.

The FSMM program may involve the following:

## A. ONE-TIME CONDUCT OF MEDICAL MISSION

FSMM is usually a one\_time activity whereby foreign missioners in partnership with a local partner usually a local government unit, non-government organization, a hospital, or medical society choose a specific area in the country to conduct their missions. The mission is usually composed of medical team of overseas based Filipinos and foreign nationals who shall practice their profession in the country for humanitarian reasons. They usually provide medical services and/or surgical procedures with specialized services like dental, cataract/eye care or cleft palate surgeries. There also instances wherein a foreign medical expert is invited to perform actual surgical procedures to indigent patients or conduct lectures, fora, symposia, seminars during their missions for the purpose of transferring technology or for continuing medical education. These are usually implemented in short durations or as temporary health care delivery.

## B. "ADOPT A HOSPITAL" PROGRAM

While one-time/short duration FSMMs are currently undertaken, a more structured program of FSMM implementation through the "Adopt a Hospital" program is now being encouraged.

The "Adopt a Hospital" program is envisioned to provide a more sustainable and longer-term approach of delivering health services to underserved communities as another form of implementing FSMM. It is undertaken through a collaborative partnership strategy between a local public hospital with a foreign - based organization/ non-profit medical mission group or foreign-based hospital.

Under this strategy, a foreign-based organization / a non-profit medical mission group / a foreign-based hospital, to be known as the <u>Partner</u>, shall identify and collaborate with a local public hospital, to be referred to as the <u>Recipient</u> <u>Hospital</u>, The selected Recipient Hospital shall be drawn from the list provided by the DOH. The collaboration shall be covered by a Memorandum of Agreement, which shall include commitments, as well as the roles and responsibilities of the concerned stakeholders in the conduct of these particular activities such as:

- 1. Provision of voluntary health services direct medical/surgical services, community-based promotive and preventive care and services or clinical rounds and hands-on operative services
- 2. Enhancing capacity of host staff and technology transfer through:
  - a. conduct of teaching programs/ medical education lectures and mentoring activities
  - b. opportunities for observation visits at the foreign based hospital funded through grants

3. Donation of required medicines, supplies, equipment and devices in due consideration of rules and regulations governing taxes and duties

## IV. IMPLEMENTING MECHANISMS

## A. ROLES AND RESPONSIBILITIES:

The following are the roles and responsibilities of the different agencies/ organizations:

- 1. BIHC FSMM Unit :
  - a. Act as the Central Coordinating body for the implementation of FSMM in the country. BIHC shall coordinate with concerned stakeholders for the smooth and successful implementation of FSMMs. It shall also facilitate the approval and signing of the Memorandum of Agreement under the Adopt a Hospital Program.
  - b. Develop policies and guidelines for the implementation, monitoring and evaluation of FSMM.
  - c. Facilitate the issuance of Food and Drug Administration (FDA) clearance on corresponding medicines, medical supplies and equipment brought by the partner mission groups/hospital including Bureau of Customs clearance for those donations consigned to the DOH. (please refer to DOH AO No. 54-A s. 2003 and DOH AO No. 2007-0017 s. 2007).
  - d. Institutionalize an interactive FSMM website that shall facilitate application and program operations among all partners/ potential partners in coordination with the Information Management Service (IMS).
  - Maintain a database/ information system for all FSMMs for easy reference, monitoring and evaluation.
  - f. Prepare regular /timely reports for the Office of the Secretary.
- 2. Centers for Health Development
  - a. Oversee the conduct of FSMM at the identified areas/ hospital under their areas of responsibility.
  - b. Provide the Local Partner/Host a list of indigents under the NHTS in coordination with the DSWD Regional Office.
  - c. Facilitate linkages of the Partner Mission Group/Hospital with the local chief executives/ congressional representative as well as the Chief or Director of the Host Hospital and also the other medical professional groups such as the Philippine Medical Association.
  - d. Assist in monitoring and evaluation of all FSMMs and ensure regular M/E reports are submitted to the BIHC FSMM unit.
- 3. Philippine Health Insurance Corporation (Philhealth) under the National Health Insurance Program shall develop policies, programs and systems to maximize reimbursement for hospital services incurred during FSMMs.
- 4. The Professional Regulation Commission (PRC), a government agency mandated to regulate the practice of profession in the country, shall facilitate the issuance of a Special Temporary Permits to foreign health professionals for the practice of

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profession during the conduct of FSMM in the Philippines. The PRC shall also regulate the practice of profession of those Filipino citizens conducting FSMM in the country but are based abroad. The PRC International Affairs Division (IAD) will provide feedback to the BIHC FSMM Unit on the list of mission groups and missions issued Special Temporary Permits (STPs), those who applied for but did not retrieve their STPs, and those whose requests were denied or disapproved.

- 5. The Commission on Filipinos Overseas (CFO), a government agency mandated to promote and uphold the interests of overseas Filipinos and strengthen their ties with the Motherland, shall be in-charge of the following:
  - a. Assist the FSMMs group on the requirements of concerned agencies on matters pertaining the conduct of FSMM in the Philippines.
  - b. Coordinate with Filipinos Overseas (OFs) groups on the requirements of concerned government agencies on matters pertaining to the processing of overseas donations.
  - c. Assist FSMMs in the facilitation of the Registration with the DOH, and Special Temporary Permits (STP) with the PRC.
  - d. Provide inputs in the database of FSMM and the FSMM website; Liaise with the FSMMs, DOH, PRC, and the local partner/hospital/NGOs/LGUs on the post-mission report and other concerns.
  - e. Assist DOH (especially BIHC-FSMM Unit) in the development and enhancement of the FSMM website and FSMM databank.
- 6. The DILG through the provincial or municipal offices shall provide logistics for the conduct of FSMM in their respective localities.
- 7. Local Partner or Host (LGU, Local NGO/Local Hospital)
  - a. Submit a letter of intent together with an Annual Plan of Medical Mission to BIHC at least four months before the conduct of mission. The conduct of FSMM must also be confirmed with the BIHC at least one month before the conduct of mission.
  - b. In coordination with the foreign mission group, submit the documentary requirements for the issuance of Special Temporary Permits and government clearances for foreign donation.
  - c. Lead the community preparations and provide logistics and technical assistance for the FSMM.
  - d. Coordinate with CHD/DSWD for the identification and screening of targeted beneficiaries.
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  - e. Prepare and submit the Post Mission report to the BIHC FSMM Unit. The Post Mission Report must be duly endorsed by the Chief of Hospital.
  - f. Responsible for the provision of long-term follow up patient care and referrals for post- operative complications.
- 8. Foreign Individual/ Mission Group
  - a. Designate a leader/head of mission who shall be responsible and accountable for the selection of members/volunteers including monitoring the performance of its team during FSMM

- b. Responsible for the authentication by the Philippine Embassy/Consulate of the documentary requirements for the issuance of Special Temporary Permit of the members of medical mission team and government clearances relative to the foreign donations.
- c. Provide list of the members of the FSMM mission group including the dates of their arrival to the Philippines and their flights details to the BIHC/CFO.
- d. Provide voluntary health services, hands on clinical/operative services, capacity enhancements and educational lectures and the necessary logistics such as medicines, medical supplies and/or equipment during the mission.
- e. Responsible for the overall actual conduct and implementation of the FSMM.
- B. PROCESSES AND STEPS

The following are the processes /steps in implementing FSMMs:

- a. One-time conduct of FSMM
- 1. The local host/partner submits letter of intent together with the Annual Plan of Mission to BIHC FSMM Unit at least four (4) months before the mission. The letter of intent should specify the type, date and exact venue of mission.
- 2. The local host/partner submits to Professional Regulation Commission the required documents (see Annex A) for the issuance of Special Temporary Permits (STP) for its health service providers pool. The processing and issuance of STP will take a lead time of 10 working days from its receipt of the complete documents.
- 3. The local host/partner confirms to DOH-BIHC the place, date, time and duration and the list of the members of the mission (one month before the
- 4. The local partner/host submits to the hospital director/DOH Representative a post-mission report within 15 working days after the mission for onward
- b. "Adopt-A-Hospital" Program
  - 1. The foreign missioner individual/group submits a letter of intent to participate in the program to BIHC.
  - 2. BIHC coordinates with concerned parties.
  - 3. Concerned parties perform their respective roles and responsibilities and implement their commitments as identified in the MOA.

## VI. MONITORING AND EVALUATION

The DOH - BIHC FSMM unit shall develop a monitoring and evaluation system to be able to keep track of FSMM implementation in the country. Under this M/E system activity reports must be submitted by the Local Partner /Host on a regular basis detailing out a summary of the FSMM activities including health services conducted and patient diagnosis (per Annual Plan). In addition, the FSMM Completion Report after the end of the FSMM period with recommendations shall also be submitted. These post mission reports shall be the basis for assessing progress and improving FSMM program implementation

#### VII. REPEALING CLAUSE

The provisions of the previous Joint Administrative Order No 2009-0030 which are not contrary to the provisions of this Administrative Order shall remain in effect.

#### VIII. EFFECTIVITY

This Order takes effect immediately.

ENRIQUE T. ONA, M.D.

Secretary of Health

Annex A.

#### DOCUMENTARY REQUIREMENTS FOR SPECIAL TEMPORARY 1. PERMIT

The Local partner/coordinator applies for the issuance of Special Temporary Permits (STPs) for its foreign medical members of the team by submitting the documentary requirements to the International Affairs Division of the PRC. Issuance of STPs is within 10 working days upon submission of complete documents.

- a. Letter of Request for the issuance of Special Temporary Permit (STPs) with the undertaking that no fees shall be charged. The letter must indicate the specific date, venue and type of humanitarian mission
- b. Authenticated Copy of applicant's valid passport as proof of citizenship
- c. Authenticated Copy of valid professional license issued from the country of origin with official English translation thereof where necessary
- d. Duly accomplished and notarized STP application form (can be downloaded at <u>www.prc.gov.ph</u>)

# 2. DOCUMENTARY REQUIREMENTS FOR FOREIGN DONATIONS

For foreign missioners who will bring medicines, supplies and equipment for the mission or for donation, the following documents must be submitted to the Bureau of International Health Cooperation, Department of Health :

- 1. Letter of request for the issuance of government clearance
- 2. Authenticated Deed of Donation and Acceptance
- 3. Shipping documents such as Bill of Lading. Airwaybill, commercial invoice and packing List
- 4. Inventory of donations
- 5. Allocation List of intended beneficiaries

#### Annex B

#### **Contact Persons**

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

FEB 2 4 2016

#### ADMINISTRATIVE ORDER

No. 2016- 0004

### SUBJECT: <u>Revised Guidelines in the Facilitation and Management of Foreign</u> <u>Donations involving Health and Health-Related Products</u>

#### I. RATIONALE

The Department of Health (DOH), through the Bureau of International Health Cooperation (BIHC), currently facilitates all foreign donations following Administrative Order (AO) 54-A s. 2003, "Guidelines on the Processing and Clearance of Importations through Donation by the Department of Health." AO 54-A aims to rationalize and systematize the acceptance of foreign donations in support of the services and programs of the health sector. It is consistent and in accordance with the Tariff and Customs Code of the Philippines (TCCP) as amended, National Economic Development Authority (NEDA) Board Resolution No. 57 s. 1988, Office of the President Memorandum No. 36 s.1992, the 1999 World Health Organization (WHO) Guidelines for Drug Donations, and Section 13 of the General Appropriations Act (GAA) of 2002, under General Provisions on Donations.

Pertinent laws and guidelines relevant to the facilitation and management of foreign donations have been passed after 2003, such as Executive Order (EO) 482 of 2005 on the National Single Window, Republic Act (RA) 9711 – The Food and Drug Administration (FDA) Act of 2009, Department of Social Welfare and Development (DSWD) AO 11 s. 2012 "Revised Guidelines on the Management and Processing of Donation", Joint Circular No. 7 – 2012 of the Department of Budget and Management (DBM) and Department of Finance (DOF), and the annually approved General Appropriations Act specific issuances and provisions on donations Hence, there is a need for certain provisions of relevant post-2003 laws and guidelines on foreign donations to be incorporated and harmonized with the current guidelines of the DOH.

In the light of increased assistance from various international partners, the DOH recognizes the importance of strengthening existing systems in the facilitation and management of foreign donations. To address current gaps and issues identified in the processing and clearance of foreign donations, there is a need to institutionalize mechanisms to promote transparency, accountability, efficiency and responsiveness. There is a shift in the paradigm from the current donor-driven system of accepting foreign donations towards a health system needs-based approach.

#### II. OBJECTIVES

#### **General Objective:**

Enhance the systems involved in the facilitation and management of foreign donations

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- 7. Deed of Donation is a duly authenticated document or instrument (authentication done by the Philippine Embassy/Consular Office at the country of origin), which when delivered gratuitously transfers ownership and interests in property to persons and/or entities.
- 8. National Single Window is an Internet-based system that allows parties involved in trade to lodge information and documents with a single entry point to fulfill all import, export, and transit-related regulatory requirements whose aim is to create a more efficient process for the importation and export of goods and to lessen the bureaucratic red tape in government agencies.
- 9. Packing List is a shipping document that contains the quantity and kinds of packages, their contents, the net and gross weight in kilograms, the full dimensions and size of each package. It supplements the commercial invoice when numerous items are being shipped or when the quantity, weight or content of articles in a shipment vary.
- 10. Pro Forma Invoice is a draft invoice given by the shipper/donor to an importer/donee/ recipient/consignee prior to the shipment of goods. It provides information on the nature, quantity, value and weight of goods to be donated.

#### V. GENERAL GUIDELINES

- 1. All donations shall be based on the following four core principles, as stipulated in the WHO Guidelines on Foreign Donations:
  - a. Maximum benefit to the recipient
  - b. Respect for wishes and authority of the recipient
  - c. No double standards in quality
  - d. Effective communication between donor and recipients
- All foreign and foreign-based Filipino donors shall abide by the existing national laws and regulations of the Philippines and shall be guided by the Paris Declaration on Aid Effectiveness, emphasizing alignment of donor systems to the procedures of recipient countries.
- 3. All donations shall be aligned with DOH thrusts and programs.
- 4. All donations shall be based on the actual expressed needs of recipients, rather than being donor-driven.
- 5. All offers of foreign donation shall be processed on a per shipment basis. The acceptance of donations should consider expiration dates that will allow adequate time for distribution and utilization among beneficiaries.
- 6. All donations shall preferably be brand new.
- 7. Proper clearances and approval shall be obtained from relevant agencies **prior** to shipment and are subject to inspection **upon arrival**. All required documents must be submitted prior to the release of any foreign donation to recipients. In cases of undeclared goods upon inspection, the donor shall be meted with a corresponding penalty and shall be blacklist.d.
- 8. All donations are subject to customs duties, taxes and other fees and charges and therefore, not accepted for free. A clear, explicit consignment arrangement on who will shoulder duties and taxes and all other costs to be incurred like brokerage, storage fees and demurrages must be established before shipment is made.
- 9. The consignee is deemed the owner of the donation and shall pay the taxes and duties and all other shipping costs unless there are other arrangements.

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## 2. Foreign Donations Consigned to DOH

Donations consigned to the DOH are approved by the Secretary of Health on a per shipment basis. Customs duties and import taxes are paid by the DOH through Automatic Appropriation. There are two subtypes in this category:

## a. DOH Consigned and Managed Foreign Donations

These are donations intended for the DOH, its attached agencies and retained hospitals. DOH facilitates the donations' clearance, release, distribution and delivery through its official broker. DOH has the prerogative to decide on where to distribute the donated items.

## b. DOH Consigned but non-DOH Managed Foreign Donations

These are donations intended for non-DOH institutions like LGUs, NGOs and non-profit health facilities but are consigned first to the DOH under special circumstances. This consignment may be approved by the Secretary of Health only if the donation is not for commercial use and offered to be used by the LGU/NGO for free. Other fees and charges such as brokerage, storage, handling, demurrage, etc., are paid by either the donor or recipient. The recipient is responsible for the management of the donation.

# 3. Foreign Donations Accompanying Foreign and Surgical Medical Missions

These are donations to be utilized in duly cleared foreign surgical and medical missions. Importation costs are paid by either the missioners or local beneficiaries unless if it is under the "Adopt-a-Hospital" Program as stipulated in AO 2012-0030, where DOH shoulders the importation costs.

## 4. Foreign Donations under Foreign Assisted Projects

These are donations facilitated through development partners, as part of the implementation of FAPs. The customs duties, import taxes and all other fees are covered by either donor (development partner) or recipient (DOH), as stated in the Project financing agreement.

## 5. Foreign Donations during Emergencies and Disasters

These are donations facilitated in times of emergencies, disasters and calamities. The customs duties and import taxes are shouldered by the government through relevant mechanisms, such as, but not limited to, charging to the Office of the President under PMO 36, the concerned National Government Agency or the One Stop Shop facility.

# C. BASIC PROCESS OF FACILITATION AND MANAGEMENT OF FOREIGN DONATIONS

All foreign donations shall undergo the following basic processes:

Step 1. Securing of initial clearance from the DOH for acceptance of donation Step 2. Submission of complete documentary requirements by the donor

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- g. Prepare the Invoice Receipts for the distribution/turnover of the foreign donations to recipients
- h. Furnish the BIHC and the Finance Service of the copies of the Invoice/Delivery Receipts duly signed by recipients
- i. Together with BIHC, review and update guidelines relevant to the processing and management of foreign donations

#### 3. FOOD AND DRUG ADMINISTRATION

- a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria
- b. Issue an initial clearance for the acceptance of proposed foreign donations consigned to DOH
- c. Issue the FDA clearance to BOC for the release of the foreign donation from the consignee's warehouse for non-DOH-managed donations
- d. Conduct physical inspection and collect samples for FDA analysis (for food and medicines)
- e. Conduct actual testing on the functionality of medical equipment and devices consigned to DOH
- f. Issue the Certificate of Product Registration, if applicable
- g. Ensure that relevant FDA policies are updated and disseminated

#### 4. PHARMACEUTICAL DIVISION

- a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria
- b. Review list of medicines intended for foreign donations and issue initial clearance for the acceptance of proposed foreign donations based on the PNF List and their existing guidelines
- c. Develop and update guidelines on foreign donations for orphan drugs
- d. Develop and issue advisories in the rational use of medicines

## 5. HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

- a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria
- b. Validate the list of equipment needed by the DOH recipient facilities based on the set standards for hospitals. Please refer to "Annex C."

## 6. HEALTH FACILITY DEVELOPMENT BUREAU

- a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria
- b. Make recommendations on the need for medical equipment and devices of health facilities using the Health Facility Enhancement Program of the DOH as basis

#### 7. FINANCE SERVICE

a. Facilitate special allotment release order request to the DBM for the automatic appropriation and charging of customs duties and import taxes of DOH Consigned donations

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- c. In coordination with the donor, submit to BIHC a letter of concurrence/ acceptance of the foreign donation and subsequently, a duly notarized Deed of
- d. Together with the donor, assume full responsibility for the payment of customs duties and taxes, fees, and other charges (i.e. brokerage fees, storage fees, etc.)
   e. Identify a designated
- e. Identify a designated or authorized broker and execute an Affidavit/Deed of Undertaking for DOH consigned but non-DOH managed foreign donations
- f. Submit to BIHC, copy furnished the RO, within 30 days after the turn-over and/or issuance of Invoice/Delivery Receipt, a Post-Donation Report duly signed by the receiving authority referred to in "Annex D".



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## SEPARABILITY CLAUSE

If any provision of this AO is declared invalid or unconstitutional by the appropriate authority or courts of law respectively, the other provisions not affected thereby shall remain valid and subsisting.

## REPEALING CLAUSE

This Administrative Order repeals AO No. 54-A s. 2003.

## EFFECTIVITY DATE

This Order shall take effect fifteen (15) days after publication in an official gazette or a newspaper of general circulation.

**JANETTE** ETO-GARIN, MD Secretary of Health

- b. Must not be expired
- c. Must be accompanied by technical specifications/dossier
- d. Must be mercury free/CFC free, if applicable

#### II. Health Related Products

#### 1. Ambulances and Mobile Clinics

- a. Preferably brand new; if second hand, must be operational/functional, in good running condition, with mileage not exceeding 50,000 kilometers and not more than three years
- b. Must have a Commercial Invoice or Certificate of Registration from country of origin
- c. Must have a recent Certificate of Quality Control/Certificate of Compliance to Emission Standards from country of origin
- d. Must have left-hand drive positioning
- e. Must have a local after-sales service provider, with spare parts, accessories and consumables that are locally available

## 2. Other Health and Health Related Products

These shall be based on the criteria set by relevant agencies and evaluated on a case-to-case basis.

#### ANNEX C. DETAILED PROCESS OF FACILITATION AND MANAGEMENT OF FOREIGN DONATIONS

# STEP 1. SECURING INITIAL CLEARANCE FOR ACCEPTANCE OF DONATION FROM DOH

i. Donor submits to the DOH-BIHC the following documents:

a. Letter of Intent to Donate addressed to:

The Secretary of Health

Attention: Director IV, Bureau of International Health Cooperation Bldg. 3, San Lazaro Compound

Rizal Ave., Sta. Cruz, Manila

- b. List of items to be donated/Packing List, providing the following minimum information, taking into consideration the requirements/criteria set in Section A:
  - b.1. For pharmaceuticals Generic name, dosage, form and strength, quantity and expiration date
  - b.2. For medical equipment and devices Technical specification, model number, manufacturing date and invoice receipt or certificate of good operating/functional condition (if second hand), and brochures and manuals written in English
  - b.3. For transport vehicles Certificate of Registration from country of origin, mileage information and photo of ambulance or mobile clinic
  - b.4. For food Quantity and expiration date
- c. Letter of Concurrence/Acceptance from the recipient/beneficiary
- ii. BIHC acknowledges receipt of letter and other documents and evaluates the request and its attachments as to completeness and conformity to the set criteria.
  - a. If there is no intent for consignment to DOH and found in compliance with existing requirements, BIHC endorses the documents to relevant offices (i.e. FDA, PDEA, Pharmaceutical Division) for the issuance of initial clearance for acceptance of donation.
  - b. If foreign donation is intended for consignment to DOH, the BIHC will seek the approval of the Secretary of Health.

The TWG, through the BIHC, shall then make a recommendation to the Office of the Secretary regarding the acceptance or non-acceptance of the foreign donation. Upon receipt of the OSEC decision, BIHC informs the donor of the decision, as well as further requirements and next steps to be undertaken.

## STEP 2. SUBMISSION OF DOCUMENTARY REQUIREMENTS

- i. Upon receipt of the approved initial clearance (for regular non-DOH consigned donations) or OSEC approval for consignment (for DOH consigned donations), the donor proceeds with the processing and submission of the following documentary requirements to the BIHC:
  - a. Original copy of the Deed of Donation duly authenticated by the Philippine Embassy/Consular Office at the country of origin
  - b. Original copy of shipping documents such as bill of lading, air way bill, pro forma or commercial invoice (if already available)
  - c. Proposed allocation list
  - d. Affidavit/Deed of Undertaking, if necessary
  - e. Designation letter of authorized broker (for DOH consigned but non-DOH managed foreign donations)
- ii. BIHC acknowledges receipt of documentary requirements and evaluates them as to completeness and veracity prior to processing.

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## c. For Foreign Donations Accompanying Foreign Surgical and Medical Missions

- Donations to be used for FSMM which are consigned to the donor and/or beneficiary shall follow the same procedures under Step 4, letter a, stated as *"Foreign Donations Not Consigned to DOH"*.
   Donations under the "Adapter Hereit and the same procedures under Step 4.
  - i. Donations under the "Adopt a Hospital Program" wherein DOH is the consignee shall follow the same procedures under Step 4, letter b, stated as "Foreign Donations Consigned to DOH".

## d. For Foreign Donations under Foreign Assisted Projects

Donations under FAPs shall also follow procedures in Step 4, letter a, if it is consigned to the concerned donor and Step 4, letter b, if it is consigned to the DOH.

## e. For Foreign Donations during Emergencies and Disasters

Donations intended for victims of emergencies and disasters shall follow DOH AO 2007-0017, "Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations" and/or other relevant existing guidelines. It shall be processed accordingly, such as, but not limited to, charging of customs duties and import taxes to the Office of the President under PMO 36, or the concerned National Government Agency at the One-Stop-Shop facility established at the major ports.

## STEP 5. INSPECTION AND FINAL CLEARANCE BY FDA

- ii. Upon arrival at the port of entry, the FDA conducts an initial physical inspection as a requirement for the release from the port of the donated pharmaceuticals and medical devices and equipment. If the port of entry of the donation is outside Metro Manila, the said inspection shall be conducted by the concerned Regional FDA office.
  iii. Aside from inspective etc. The same set of the same
- Aside from inspection, the FDA also collects samples of pharmaceuticals at the consignee's warehouse for analysis.
   For medical aminor of analysis.
- iv. For medical equipment and devices, the FDA conducts actual testing on the functionality of the donated items at the recipient facility, prior to issuance of necessary licenses.
   v. If the FDA finds the donated item to be accurately and the second second
- v. If the FDA finds the donated items acceptable for donation after inspection, the FDA issues a final clearance for the release of the donated health and health related products. No donation shall be released from any warehouse and distributed without the FDA clearance.

## STEP 6. RELEASE AND TURN OVER TO CONSIGNEE

- The DOH-LMD is responsible for the delivery, proper turnover and distribution to the ultimate recipients of DOH consigned and managed donations once released from the port by the BOC. It issues an Invoice Receipt which will be signed by the recipient for accounting and monitoring purposes.
- ii. For DOH consigned but non-DOH managed donations, the DOH-LMD coordinates with the identified authorized broker of the donor or recipient regarding the DOH payment of customs duties and import taxes and the release of the shipment. The broker must submit to the DOH-LMD a Delivery Receipt for accounting and monitoring purposes.

# ANNEX D. POST-DONATION REPORT FORM

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Position				
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# Documentary Requirements for the conduct of Foreign Surgical and Medical Missions

#### Letter of Request

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Indicate type (medical, surgical, dental), date and exact venue of mission. Please address the letter to:

MS. MAYLENE M. BELTRAN, MPA, CESO III Director IV Bureau of International Health Cooperation

#### Special Temporary Permits (STPs)\* Provide scanned copies of STP Resolutions as issued by the Professional Regulation Commission.

## Letter of Acceptance/Confirmation from Local Partner

Confirm to DOH – BIHC the place, date, time and duration of mission. Include a list of all members of the mission. Please address the letter to:

MS. MAYLENE M. BELTRAN, MPA, CESO III Director IV Bureau of International Health Cooperation

#### Post Mission Report

Submit to DOH Representative (Regional Office) a post-mission report within 15 days after the mission for onward transmittal to DOH-BIHC

# Checklist of Requirements for the Application of Special Temporary Permits (STPs)

Letter of Request for the issuance of STP with undertaking that no fees shall be charged to patients. The letter must indicate the specific date, venue and type of humanitarian mission (medical, surgical, dental). Please address letter to:

> Hon. Teofilo S. Pilando, Jr. Chairman Professional Regulation Commission P. Paredes St. cor. Morayta St. Sampaloc, Manila

Tel. (632) 3100026 Telefax (632) 7354476 www.prc.gov.ph

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- □ Copy of applicant's valid passport as proof of citizenship
- Authenticated Copy of valid professional license issued from the country of origin with official English translation, if necessary
- Duly accomplished and notarized STP application form



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

Code: 2016 FDR \_\_\_\_\_

### Donor's Checklist For Foreign Donations Seeking Food and Drug Administration Clearance :

Submit to Bureau of International Health Cooperation (BIHC) the following documents for processing of request for FDA clearance:

1.	Letter /email of intent/request addressed to
·	Dir. Maylene Beltran
	Director IV
	Bureau of International Health Cooperation
	Building 3, San Lazaro, Compound, Sta. Cruz,
	Manila, Philippines
	Telephone No. (63 2) 6517800 local 1302/1352
	Email address: mbeltran.bihc@gmail.com
2.	Detailed list of items to be donated
	For medicines - with 12 months minimum expiration date, properly labeled in original packaging, with texts in English
	For medical equipment and devices - with detailed specifications, of quality, if second hand, must be certified to be in good operating/functional condition
3.	Distribution Plan of Commodities
4.	Deed of Acceptance from the recipient/beneficiary facility
<u> </u>	
5.	Deed of Donation duly authenticated by the Philippine Embassy /Consulate in the Country of Origin
6.	Shipping documents – includes packing list, bill of lading/air waybill, commercial invoice

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 6517800 Direct Line: 711-9501 Fax: 743-1829; 743-1786 • URL: <u>http://www.doh.gov.ph;</u> e-mail: <u>asec@doh.gov.ph</u>