

## PHILIPPINE GENERAL HOSPITAL

The National University Hospital University of the Philippines Manila Taft Avenue, Manila

PHIC Accredited Health Care Provider ISO 9001 Certified

## TERMS OF REFERENCE

# FOR CONSIGNMENT OF VARIOUS MEDICAL DEVICES FOR CENTRAL ENDOSCOPY UNIT

#### I. PROJECT DESCRIPTION

PGH is in need of a **CONSIGNOR** to consign a brand new medical devices for the Department of Ophthalmology and Visual Sciences of the Philippine General Hospital.

For this purpose, the project medical device shall be understood as "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  - Investigation, replacement, modification, or support of the anatomy or of a physiological process;
  - Support and sustenance of life, control of conception, or disinfection of medical devices;
  - Provision of information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body
- b) Which does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means, but which may be assisted in its intended function by such means.

The number of source/s for **CONSIGNOR**/s, whether single or multiple shall be determined by the PGH-Consignment Committee.

Multiple sources shall be allowed in instances when the responsive **CONSIGNOR** with the lowest price offer cannot adequately fill-up the quantity demanded by the Hospital within a given consignment period.

In case that the contract is awarded to multiple sources, the schedule shall be set on the sourcing of said item(s) from all the **CONSIGNOR**/s. However, identification of specific **CONSIGNOR**/s may be allowed for items considered highly specialized, or where small

variations may significantly influence the safety, efficacy, and general outcome of the treatments or procedures where the item will be used, provided that it is supported with valid justification by the respective Department Head and approved by the PGH Director.

#### II. CONTRACT DURATION

The Consignment Agreement shall be valid for one (1) year, renewable subject to satisfactory performance to be recommended by the Consignment Committee and approval by the Director.

## III. ELIGIBILITY REQUIREMENTS (Please refer to ANNEX A)

#### IV. SCOPE OF WORK

Ensure high quality, brand-new, timely or immediate delivery, and stock availability of the medical devices for operational use of the said selected clinical departments at reasonable prices based on the Consignment List (*Please refer to ANNEX B*)

#### V. TERMS AND CONDITIONS

- 1. The **CONSIGNOR** shall be required to fulfill the following:
  - 1.1. Deliver, as the need arises, brand-new medical devices indicated in the consignment orders;
  - 1.2. Deliver variable items (as to size, models, quality) to be confirmed by the Doctor based on the actual need of the patient/s in case the items to be used are not yet determined due to compatibility concerns, which will then be reflected in the Consignment Order;
  - 1.3. Deliver/supply consigned items within 48 hours upon receipt of order, with commitment to stock availability;
  - 1.4. Deliver a "custom-made medical device" which refers to a medical device, other than a mass-produced medical device, that is.—
    - (i) Assembled or adapted in the manner that is intended for individual patient; or
    - (ii) Specially fabricated or imported for the sole use of a particular person, in accordance with the specifications of a qualified practitioner;

- 1.5. Open to inspection and/or testing of all deliveries by the PGH to the extent practicable and necessary prior to acceptance;
- 1.6. Comply with the security, safety, and PGH house rules related to the issuance of medicines and other pharmacy products to patients;
- 1.7. Is subject to the investigation and submission of report/s to PGH for any incident or medication safety issue related to the activities done by the **CONSIGNOR**;
- 1.8. Relieve the PGH from any responsibility for any loss of consigned items arising from fortuitous events beyond the control of the PGH; provided, however, that such loss is not due to negligence resulting to theft or pilferage, and in which case the PGH Pharmacist-on-Duty/Nurse-on-Duty/Administrative Officer-on-Duty, or those staff physically present within the immediate vicinity of incident, including the security guards shall be held jointly and severely liable for the monetary value of the goods pilfered/stolen;
- 1.9. Certify that all the documents submitted are complete and authentic copies of the original, and that all statements and information provided therein are true and correct
- 2. The consigned items shall be delivered and accepted as follows:
  - 2.1. *Just-In-Time Inventory Item*/s<sup>1</sup> the **CONSIGNOR** agent delivers item directly to Operating Room (OR)/Procedure Supply Center;
  - 2.2. Non-General/Special Inventory Item/s<sup>2</sup> the CONSIGNOR delivers initial stock items to OR/Procedure Supply Center and the item shall be inspected immediately together with the representatives of the Internal Audit Services Staff (IASS) assigned to do inspection; and
  - 2.3. General Inventory Item/s (Property and Supply Division or PSD Floor Stocks)<sup>3</sup> the CONSIGNOR delivers initial stock items to PSD Warehouse and the items shall be inspected immediately together with the representatives of the IASS assigned to do inspection.
- 3. The **CONSIGNORs** are prohibited from the following acts:

<sup>&</sup>lt;sup>1</sup> Item V. (11) of the Consignment Guidelines, *Just in Time Inventory* - refers to the inventory management system where items are made available only when the need for the item arises and no stocks are kept on standby.

<sup>&</sup>lt;sup>2</sup> Item V. (17) of the Consignment Guidelines, *Special/Non-General Inventory Item/s* - refers to the inventory management system where special use supplies are directly requested by concerned department/area and made available as floor stocks to cater the needs of individual patients and usage\_charged directly by the OR/Procedure Supply Center to their patients' accounts.

<sup>&</sup>lt;sup>3</sup> Item V. (10) of the Consignment Guidelines, *General Inventory Item/s (PSD Floor stocks)* - refers to the inventory management system where items are made available to a) wards/areas through their respective departments; regarded as floor stock items considered to be part of the operational costs and not charged to individual patients, and b) supply outlet, charged items used to individual patients.

- 3.1. Offer/Deliver "counterfeit medical device", that is, a medical device, the label or outer packing of which is an imitation of, or resembles or so nearly resembles that of another medical device, as calculated to deceive into believing that it is the label or outer packing of a medical device of another manufacturer;
- 3.2. Offer/Deliver "misbranded medical device", that is, a medical device
  - (a) Which is not labelled in the prescribed manner;
  - (b) Which has on the label or labelling, any word, statement, other matter or information required by these rules, to appear not prominently or with such conspicuousness as compared with other words, statements, designs, or devices on the label or labeling, and in such terms as may render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
  - (c) Which is not labeled with directions for use and such warnings against use in indications wherein its use may be dangerous to health, or against unsafe administration or application, in such manner and form as are necessary for the protection of users, or as may be prescribed;
  - (d) With a label or container, or anything accompanying which, bearing any statement, design, or device which makes any false claim for the medical device or which is false or misleading in any particular; or
  - (e) Which is so colored, coated, polished, or treated that damage is concealed, or which is made to appear of better or of greater performance than it really is;
- 3.3. Offer/Deliver "substandard medical device", that is, a medical device that is not of specifications;
- 3.4. Offer/Deliver "refurbished medical device", that is, a medical device that was previously owned and reconditioned for resale, even if it meet the safety and performance parameters set by the manufacturer

# VI. TERM OF REMITTANCE OF THE SALES PROCEEDS

All payments shall be referred to the payment provision of the Consignment Agreement that is "the consignee agrees to remit the sales proceeds to the **CONSIGNOR** in fourteen (14) days, after receipt of any of the following, whichever is applicable:

- (a) Receipt by the consignee of the funds from the funding agency/ies;
- (b) Receipt by the consignee of the patient's payment."

#### VII. PARTICIPATION FEE

A complete set of Consignment Documents may be acquired by interested Consignors from the PGH Consignment Office upon payment of the participation fee in the amount of Ten Thousand Pesos (PhP10,000.00) as per Memorandum No. 2018-118.

It may also be downloaded free of charge from the website of the <u>Philippine General Hospital</u>, provided that Consignors shall pay the applicable fee for the Consignment Documents not later than the submission of their consignment offer.

### VIII. POINT OF CONTACT

The **CONSIGNOR** will liaise with only six (6) offices and will receive Job orders only from the following:

- 1. Office of the Deputy Director for Health Operations Represented by the Deputy Director, **Dr. Rodney B. Dofitas**;
- 2. Central Endoscopy Unit Represented by the Head, Dr. Ma. Lourdes O. Daez;
- 3. PGH-Consignment Committee Represented by the Chairperson, **Dr. Peter B. Bernardo**; and
- 4. PGH-Consignment Unit Represented by the Head, Ms. Maria Bernadette P. Idjao

All communications and requests are to be directed to the above named individuals. The above named individuals may designate a point person-in-charge of all requests and other communications regarding the **CONSIGNOR**.

PETER B. BERNARDO, MD

PGH-CC Chairperson