1. The PGH Consignment Committee (PGH-CC) issues this Bulletin to address / clarify request/concerns change or clarify the following:

<table>
<thead>
<tr>
<th>Request(s)/Concern(s) Raised</th>
<th>Response(s)</th>
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<tbody>
<tr>
<td>In the case of items that need to be autoclaved, for which the intended procedure/operation did not materialize but the items were already exposed, who will shoulder the autoclaving expenses?</td>
<td>The cost of the autoclaving will be passed at the patient’s expenses. <em>(This should be clear to the patients as a matter of policy)</em></td>
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<td>Request for clarification regarding the Senior Citizen Discount if this will be factored-in in the offer of consignors.</td>
<td>The Senior Citizen Discount will have to be factored-in in the offer of the consignors <em>(same with the other privilege discounts for solo parents, and persons with disability)</em></td>
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<td>On items with brand names.</td>
<td>Please note that all brand names in the consignment list are hereby <strong>DELETED/DISREGARDED</strong> and only generic names of the devices shall appear in the list.</td>
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<tr>
<td>On items with no sizes as part of the specifications.</td>
<td>Please note that all sizes in the consignment list are hereby <strong>DELETED/DISREGARDED</strong> and it shall be construed that prospective consignors will be the one responsible for offering the variety of sizes in accordance with the generic names of the items.</td>
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<td>Can the ISO/ISO 13485 be certified as true copy, not by the principal manufacturer but by the distributor, because it will take time to get one from the principal manufacturer?</td>
<td>The prospective Consignor may submit what is available but this is subject to decision on a case-to-case basis.</td>
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<td>On the requirements of “with supply chain presence in major areas of the country” as stated in Item No. 3.3 in the Checklist of Requirements under Eligibility Documents, does it mean office?</td>
<td>For the purpose of clarification, the phrase “with supply chain presence in major areas of the country” shall mean operation in major islands of the Philippines <em>(i.e. Luzon, Visayas, and Mindanao)</em>, not necessarily mean an actual office.</td>
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<td>On the policy of fabricated items, can the potential consignors be allowed to participate even if they do not have a CPR?</td>
<td>As a matter of policy as stated in Item No. 14 (ii) of the Terms of Reference, which allowed for “specially fabricated or imported for the sole use of a particular person, in accordance with the specifications of a qualified practitioner”, the consignors can participate for as</td>
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- For items to be consigned under exclusive distributorship, what policy and/or requirements will be adopted?

- For those products that are new to the market, can the 5-year requirement for operation be waived?

- In addition, can the requirement of 40% foreign ownership as indicated in Item No. 3 of the Invitation to Consign be waived if the company/subsidiary is 100% foreign-owned, and thus the exclusive distributor?

- Those items under exclusive distributorship may also be consigned, provided that the consignor(s) shall provide a (1) Certificate of Exclusive Distributorship from its principal, certified as true copy whether by the principal or the distributor to be also included in the Envelope 1. This shall be subject to the provision of Item No. VIII (6) paragraph 3 of the Consignment Guidelines which states that it shall be subject to the same eligibility requirements as stated in the Annex A; and

- (2) The accomplished Consignment List / Form of the item(s) that is/are for exclusive offering.

- On the requirements of ISO 13485 – Medical Devices – Quality Management Systems for Manufacturers, can the prospective CONSIGNOR, who is not a manufacturer, submit other related ISO document other than ISO 13485?

- Can the prospective consignors submit a Certificate of Product Registration (CPR) that is near expiration?

- Requesting to remove the phrase in “whether similar in nature and complexity to the contract to be consigned” in the List of completed and all its ongoing government and private contracts, including contracts awarded but not yet started, if any, as stated in Item No. 4 in the Checklist of Requirements under Eligibility Documents

- In the case of a pioneer product that has no price yet in the local market, can the consignor state “Non-applicable” or “N/A” in the Consignment List as this requires a response?

- Request to reset the submission of

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long as there is a written endorsement from the end-user, signed by the Department Chair.

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GRANTED. Prospective Consignors may submit other ISO documents as long as these are related or similar in nature. They shall also submit the principal manufacturer’s certified true copy of ISO 13485.

GRANTED. Yes, as long as the expiration date is prior to the deadline of submission of consignment offers, provided that the renewed CPR shall be submitted prior to the preparation of consignment orders.

GRANTED. As long as the consignors have experience in the consignment system as a mode of procurement of hospital needs, even if it is not similar to the present items for consignment.

DENIED. The Committee requires the consignors to fill out all entries in the consignment list for the items they will intend to participate. For the said product, the consignor shall indicate the international rate.

DENIED. Considering the items are...
Consignment Offer from 4 April 2018 to 11 April 2018 urgently needed and should be consigned as soon as possible.

2. The following are further amended to the existing consignment-related documents:

a. In Item No. 10 in the Checklist of Requirements under Eligibility Documents “If the prospective Consignor opts to submit a Certificate issued by the PGH Bids and Awards Committee as a substitute with legal documents only for Item Numbers 1, 2, and 2 “8” while Item Number 3, 4, 5, 6, 7, 10 and 11 will be submitted separately”, please note that the 7 should actually be referring to item 8 of the said document.

b. In Item No. 3 of the Invitation to Consign: “The PGH Consignment Committee (PGH-CC) now invites eligible Consignors to submit consignment offers for the consignment of Various Medical Devices / Implants for the Different Clinical Departments for a one (1) year contract “until the end of the year” subject to renewal. The invitation to consign is restricted to Filipino citizens with at least sixty percent (60%) interest or outstanding capital stock belonging to citizens of the Philippines pursuant to Republic Act 5183 and subject to Commonwealth Act 138.”

c. Prospective consignors should only indicate items that they are bound to participate and which should be reflected in the accomplished Consignment Form / List. Please delete items with no offer.

d. Please see revised consignment list.

3. This Bulletin shall be an integral part of the Terms of Reference for this project.

Approved by:
(Sgd.)

JULIET O. SIO-AGUILAR, MD, MSc
PGH-CC Chairperson