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ADMINISTRATIVE ORDER
No. 13-C s. 1999

SUBJECT: Procurement Guidelines for Drugs and Medicines

Prior to the official organizational, functional and financial restructuring of the DOH which shall comprehensively decentralize the procurement of drugs and medicines to the Regional Health Offices (RHO), DOH hospitals and even to the LGUs, the following manner of procurement of drugs and medicines will be used by the DOH.

1. **Regionally Procured and Distributed.** Bidding and distribution will be undertaken by the RHOs using sub-allotments from the Services at the central office or the RHOs own budget. For sub-allotted funds, the central office shall be treated or given a share of at most two(2) regions which will be distributed among regions as necessary. This is subject to the same guideline including the RHO standard procurement system (AO 13-B s. 1999), guidelines on sub-allotment (AO No. 7 s 1999) and EO 302 s 1996 and other guidelines supporting this order.

2. **Centrally Procured Through A Procurement Agent and Distributed by the same agent or through the Procurement and Logistics Service.** Procurement shall be undertaken by another agency such as the Procurement Service of DBM or international non-profit organization such as the World Health Organization (e.q., leprosy drugs) or the United Nations International Children's Fund (e.q., vaccines) by transferring the funds to these organizations. This process shall be governed by AO No. 8 s. 1999 which stipulates the process of utilizing the services of procurement agents for the purchase of goods needed by the DOH, and other related guidelines.

3. **LGU Procured and Distributed.** Whenever permitted by existing government accounting and procurement rules and regulations, procurement of drugs and medicines will be further decentralized to the LGUs.

The following manner of procurement will only be resorted to when the above are proven least effective, and/or least efficient and/or not advantageous to government:

4. **Centrally Bidded but Regionally Procured and Distributed –** Bidding will be undertaken at the central office. The price list is then provided to the RHOs and hospitals. Funds for purchasing the drugs may be from sub-allotments from the central office or the RHO or the hospital's own budget. RHO will take the

responsibility of buying from the winning supplier as indicated in the price list and in accepting and distributing the drugs and medicines. This manner of procurement shall follow this guideline and other related guidelines supporting this Order and Executive Order 302 s. 1996.

5. **Centrally Procured and Distributed** by the Procurement and Logistics Service (PLS) together with the created Procurement Committees and the End-User Services. Drugs may be delivered at the central office or RHO. Distribution from the central office to RHO shall be undertaken by PLS and the Services, while further distribution shall be conducted by the RHOs. This manner of procurement shall also follow this guideline and other related guidelines supporting this Order and Executive Order 302 s. 1996. This will be the least utilized manner of procurement unless identified as the procedure most advantageous to government.

The manner of procurement shall be determined primarily by the Undersecretary and Service Director concerned with PLS and BFAD. Refer to II.2

The procurement of all other goods and services shall be governed by Administrative Order 14-b dated August 1, 1997 until further amended. However, the PLS is hereby mandated to prepare a DOH APP, that is, for PLS to consolidate all Office APPs before the procurement packages are prepared by category or the mode of procurement are decided upon.

This order sets in place the structure, terms and conditions, and responsibilities of concerned committees and units in the procurement cycle of drugs and medicines. **The RHO and DOH hospitals shall adopt the terms and conditions of this order but are given latitude to define their structure as well as responsibilities of different involved units and individuals at their level** pursuant to EO 302 s. 1996 and AO 13-B s. 1999 " Standard Procurement System in Regional Health Offices and District Health Offices of NCR of the DOH."

I. STRUCTURE

1. The following major Offices shall be held accountable and will supervise the responsible Bureaus/Services and special units/committees that shall be established and/or strengthened for the procurement of drugs and medicines. **The counterpart offices/units at the regional offices/hospitals shall take charge at that level.** Each of the Offices, Bureaus, Services represented in each Unit/Committee are jointly liable and accountable for all expected results or deliverables from the procurement process.

No	Procurement Committee/Unit	Responsible Service/Unit	Support Bureaus/Service	Accountable Officer	Answerable Supervisor	Output/ Deliverables
1	Suppliers Accreditation Unit (central office only)	Bureau of Licensing and Regulations (BLR)	• BFAD • FOFLSA • Finance Service	Director of BLR	Undersecretary (Usec) of OSR	Accreditation Certificate

No	Procurement Committee/Unit	Responsible Service	Support Bureaus/Service	Accountable Officer	Answerable Supervisor	Output/ Deliverables
2	Price Monitoring Unit (PMU)	Regulation Division I, BFAD or (equivalent in RHO / hospital (FDRO/MAA))	• NDP	Chief Regulation Division I/ (Asst Regional Director(ARD))	BFAD Director/(Regional Director (RD))	Price Monitoring Report
3	Drugs Testing	BFAD		BFAD Director	Usec of OSR	Drug clearance
4	National Drug Committee (Therapeutic Committee in RHO & Hospitals)	BFAD (Office of the ARD)	• Selected Hospital Chiefs • NDP • Representative from Specialty Societies	Program Manager, NDP/ (Chairperson of the Therapeutic Committee)	Usec. of OSR / (ARD)	PNDF Clearance, i.e., if within PNDF; Clearance of exclusiveness in case of procurement from exclusive distributor
5	Requesting Service/ (Division/Program/ Department)	Service/Division and Programs	• All other committees and units	Chief of Service/ (Section chief/ Program Coordinator)	Usec. Concerned/ (Division or Department Chief)	APP, RIV, Distribution list; acceptance report; Payment
6	Pre-qualification Bids and Awards Committee (PBAC) *[for RHO refer to AO on RHO standard procurement guidelines]*	Chairperson of PBAC (At least a third ranking official of the agency per EO 302)	• Asst. Sec. • Director of End-user Service • Director of OLA • BFAD • PLS • FOFLSA • COA • Pharmaceutical industry representative • Other experts • Secretariat	Asec of Office concerned	Usec.of Office Concerned	Prequalification report/ bidding resolutions Recommendation to award contract
7	Technical Evaluation Committee (TEC)	BFAD/NDP/ (FDRO)	• End-user Service • FOFLSA • FS	TEC Chairperson	PBAC Chairperson	TEC report/ Prequalification Report
8	Procurement Information Center (PIC)	Procurement and Logistics Service (PLS) (Administrative Division in RHO/hospital)	• PIHES • End-user services • GS,AS • MAS	Director, PLS/ (Chief of Administrative Division (AD)	Asec. Of OMS/ (RD)	Procurement documents/ announcements. Procurement references; Bulletin boards
9	Drugs and Medicines Procurement Unit	Procurement Division, PLS (Supply section, Administrative Division in RHO/hospital)	• All Committees • End-user Ser. • OLA	Director of PLS/ (Chief of Supply section, Administrative Division).	Asec. of OMS/ (Chief of Administrative Division)	Consolidated DOH APP, Bid documents;
10	Delivery and Distribution Unit • Scheduling	Division Chief of End-user Service	MMD, PLS/ (Supply Section, AD)	Director of end-user Service	Asec. Concerned/ (Chief of Admin. Div.)	Delivery schedules, Distribution List; Packing requirements
	• Hauling/ shipping	• PLS • (Supply section)	• End-user Service/ division	Director, PLS/ (Supply Section Chief)	Asec.of OMS/ (Chief of AD)	Invoice Receipt; Bill of Lading
11	Inspection and Acceptance Unit (IAU)	Material Management Division, PLS/ (Supply Section,AD)	• End-user Service Representative • BFAD/NDP	Director of PLS/ (Chief Supply Officer)	Asec.of OMS/ (Chief of AD)	Inspection Report
12	Warehousing Unit	Materials Management Division, PLS/ (Supply Section)		Director of PLS/ (Chief Supply Officer)	Asec.of OMS/ (Chief of AD)	Inventory Report

No	Procurement Committee/Unit	(Supply Section) Responsible Service	Support Bureaus/Service	Officer) Accountable Officer	AD) Answerable Supervisor	Output/ Deliverables
13	Financial Transaction Office	Finance Service/ (Financial Division FD)	• End-user Service PLS	Director of FS/ (Chief of FD)	Usec.of OMS/ (ARD)	CAF, ROA,Check
14	Suppliers Performance Evaluation Unit	Financial Operations and Front Line Services Audit/ (Management & audit analyst, ARD's office)	• PLS ▪ End-User Services • OLA	Director/ OIC, FOFLSA/ (ARD)	Asec.of OCS/ (RD)	Recommendati on on warning, suspension, debarment;
15	Grievance Committee	OCS (ARD Office)	▪ All units/ committees ▪ Users	Usec. OCS / (ARD)	Secretary of Health/ (RD)	Resolution of conflicts
16	Performance Audit Team	FOFLSA/ (MAA, ARD Office)	• PLS • End-User Service ▪ HMDTS • AS	Asec. Concerned/ (ARD)	Usec. Concerned/ (RD)	Resolutions on issues; Staff perfor-mance evaluation
	• Commendation	Asec.concerned/ (Chief concerned)		Usec./ (ARD)	EXECOM/ (MANCOM)	Awards
17	Procurement Contracts Units	OLA/ (Legal Section)	• PLS/ • (Supply Section)	Director of OLA/ (Chief ,Legal Section)	Usec.of OCS/ (ARD)	Pro-forma contracts; Procurement contracts

II. TERMS AND CONDITIONS

1. **COVERAGE:** Drugs and medicines procured by the Central Offices, Regional Health Offices and Hospitals which are used by the DOH and/or distributed to the LGUs. All purchases of drugs and medicines shall follow the Generics Law and Executive Order 49, and the Essential Drugs List (Phil National Drug Formulary Volume 1, current edition). All medicines selected by a health program which are specified to be the only exclusive and best drug available for use by the program and claimed to be exclusively distributed by a manufacturer should pass through the National Drug/Therapeutic Committee. Claimed exclusiveness can also be verified through BFAD.

   All other goods and services to be purchased are governed by AO 14 s. 1997 and/or other related issuances unless otherwise revised.

2. **MANNER OF PROCUREMENT:** The Undersecretary (or Division Chief and Regional Director) concerned together with BFAD/NDP and PLS (Administrative Division) should act as clearing house to determine manner of procurement as stated above. They should establish what is most advantageous to the government. The EXECOM (MANCOM) shall confirm such decision.

3. **SERVICES/PROGRAM COMMITMENTS:** The Services/Programs (Division/ Departments) buying the goods will be responsible for initiating and completing the purchase. Absence of a representative of the Service or Program concerned in any of the major activities (pre-bid, bidding, technical evaluation and inspection & acceptance) in the procurement process may be a reason for not proceeding with purchase of the drugs and medicines requested.

4. COMMITMENTS OF THE PROCUREMENT & LOGISTICS SERVICE AND REGIONAL/HOSPITAL SUPPLY SECTION, ADMINISTRATIVE DIVISION:

4.1 It shall consolidate the office/division drugs and medicines APPs to come up with a DOH/RHO Drugs and Medicines APP

4.2 It shall prepare all bid documents including foreign assisted projects with the assistance of the Project Management Offices.

4.3 It shall facilitate the purchase of drugs and medicines until their delivery to the intended beneficiaries.

4.4 It must make sure that individuals and offices concerned are notified in writing of the procurement activities two weeks in advance followed by a telephone call (two) 2 days before the activity.

4.5 It shall make sure that the necessary logistics and staff support are available during the pre-bid, bidding, evaluation, delivery, inspection and distribution process.

4.6 It shall maintain an archiving system for all procurement documents.

4.7 It shall maintain a suppliers track record management system which should be supplied to the Suppliers Accreditation Committee and the suppliers performance evaluation system unit.

4.8 It shall operate and maintain a computerized logistics management information system.

5. TENURE & DESIGNATION OF PBAC: (REFER TO AO 13-B s. 1999 ON RHO STANDARD PROCUREMENT)

5.1 The creation of PBAC shall follow the conditions set by Executive Order 302 s 1996.

5.2 The PBAC members shall serve a maximum of one year renewable for another year only, unless otherwise stated or terminated by the Secretary of Health or Regional Director or Hospital Chief.

5.3 The PBAC members are designated by the Secretary of Health or Regional Director or Hospital Chief and their membership shall be covered by a Department Order or Regional Order or Hospital Order respectively.

5.4 An official from the Bureau of Food and Drugs (FDRO in the RHO) shall be a permanent member of the Committee

5.5 The Secretariat of the PBAC must be highly trained and efficient personnel who will keep andcontinue the records of policies, procedures and traditions of each Committee.

6. TENURE AND DESIGNATION OF THE TEC.

6.1 A Technical Evaluation Committee (TEC) shall be created for every semester/annually to assists in the evaluation of bids for drugs and medicines.

6.2 The Vice Chairperson of the TEC shall be the PBAC member from BFAD (FDRO)

6.3 A financial analyst from the Finance Service/Division and FOFLSA (Management & Audit Analyst (MAA) at the Asst. Regional Director (ARD)'s office) shall be included in the TEC when necessary to undertake financial statements analysis primarily to determine financial capability and to ensure that the winning bidder have the financial backing for a procurement transaction, Refer to II.11.9.

6.4 The Head of Agency concerned or PBAC may designate other experts from other DOH units or external agencies to take part in the evaluation as necessary.

7. SUPPLIERS ACCREDITATION AND PRE/POST QUALIFICATION:

7.1 All suppliers of drugs and medicines shall be accredited. In cases when accreditation has not been performed the accreditation requirements shall be included in the pre-qualification process. Refer to Administrative Order 27 s 1998, Guidelines and Procedures of Government Suppliers for Pharmaceutical Products and Section 8 of this AO.

7.2 Suppliers for drugs and medicines shall be <u>centrally</u> accredited.

7.3 Suppliers accreditation shall be performed by a committee with the Undersecretary of OSR as the Chairperson and the BLR Director as Vice Chairperson.

7.4 The accreditation unit through the Undersecretary of Standards and Regulations shall submit a list of accredited suppliers regularly every month to PLS and to the PBAC at the central office and to the RHOs and hospitals. This will also be published in the DOH web-page.

7.5 The Committee shall maintain a computerized accreditation registry which can be accessed by the other procurement committees and units concerned.

7.6 A separate administrative order for suppliers accreditation will be issued including suspension and blacklisting guidelines.

7.7 Supplier accreditation is not equivalent to pre-qualification for local purchases especially in international competitive bidding.

7.8 Pre-qualification is mandatory as stipulated in EO 302 even if the bidding is with accredited suppliers.

7.9 If pre-qualification cannot be undertaken before bidding, a post qualification during bidding shall be conducted taking into consideration the accreditation and pre-qualification criteria.

8. ELIGIBLE SUPPLIERS AND REQUIREMENTS FOR PRE/POST-QUALIFICATION AND BIDDING

8.1 Only the following categories of drug manufacturers are allowed to participate in the bidding for drugs and medicines. Definitions are based on AO 56 s 1989 of the revised regulations for licensing of drug establishments and outlets .

8.1.1 Drug Manufacturer Distributor is engaged in the production of a drug, including propagation, processing, compounding, finishing, filling,

packing, repacking, altering, ornamenting and labeling with the end view of storage, distribution or sale of the products.

8.1.2 Drug Manufacturer with Distributor(s). is a drug manufacturer like 8.1.1 but do not have a marketing arm and as such utilizes a company to distribute its products

8.1.3 Drug Distributor with licensed toll manufacturer is a registered owner of a drug product, procures the raw materials and packaging components, and provides the production monographs, quality control standards and procedures, but sub-contracts the manufacture of such product to a licensed manufacturer (toll manufacturer). It also distributes or markets its products.

8.2 The following indicate who participates in the accreditation and bidding for each category of supplier in # 8.1 .

#	Supplier	Accreditation	Bidding
1	Drug manufacturer-distributor	Manufacturer	Manufacturer
2	Drug manufacturer with Distributor	Manufacturer	Distributor
3	Drug distributor with licensed toll manufacturer	Manufacturer and Drug Distributor	Drug Distributor

8.3 A manufacturer in 8.2.2 may have several authorized distributors but **only one** of them will be allowed to participate in a bidding in RHO or hospital or central office. The manufacturer shall have to inform the DOH of the authorized distributor in the particular bidding in the RHO or hospital

8.4 If a manufacturer with a distributor opts to join the bidding, then **not one** of its distributors will be allowed to participate in that particular bidding.

8.5 The following shows the **minimum** requirements/criteria for prequalification or bidding. Criteria for accreditation is in a separate Administrative Order AO 27 s 1998.

8.5.1 DRUG MANUFACTURER-DISTRIBUTOR

#	Criteria	Requirements	Countercheeks .
1	DOH accredited for at least 3 months at time of bidding	Manufacturer's DOH Accreditation Certificate .	Receipt of accreditation application is not acceptable. Check certificate with original. Should be double checked from the Accreditation Committee list
2	Valid Licensed to Operate (LTO) for at least 6 months at time of bidding	Manufacturer's valid and authenticated LTO issued by BFAD	Receipt of application is not acceptable. Should be counterchecked with BFAD regular listing
3	Drug registered in BFAD for at least 5 years	Manufacturer's valid and authenticated CPR issued by BFAD	The line product being proposed must have been registered for at least 5 years. Not allowed to participate if product has not been registered. Should be counterchecked with BFAD regular listing

#	Criteria	Requirements	Counterchecks
4	Financial capability or net worth not lower than 50% of estimated contract price	Manufacturer's duly audited financial reports for the last two years submitted to SEC and BIR (If the bidder selected as the lowest evaluated bid has a net worth below total contract price, a credit line from a reputable bank should be required)	Check with signing auditor-accountant. Also check accountant's certificate of registration from PRC or PICPA if doubtful. To be analyzed by FS and FOFLSA for financial capability.
5	Product has been produced, distributed and sold for at least five years	1. Annual production records for the last 5 years 2. Batch distribution record duly registered with BFAD of the product for the last 5 years 3. Ten sample invoices to major drug outlets preferably major drug stores, hospital pharmacy or botica the past 2 years	Check with BFAD Check with BFAD Check authenticity with drug outlet concerned
6	Current presence of the product in major drug outlets	One sample of finished product being sold in smallest unit available that approximates the unit requirement of the bidding	Check with major drug outlets if necessary. Also check for expiration date. RETURN to Bidder after physical evaluation. Check also invoices in requirement #5
7	Own raw material to be used	Records or proof of purchase of raw materials If imported: Certificate that the manufacturer is registered in the country of origin duly authenticated by the territorial Phil. consulate	Take note of country of origin if imported; and date of purchase and certificate of analysis. Check with BFAD
8	Product stability	Stability study for longer claim on expiry date of more than 2 years	Check with BFAD
9	Good track record with DOH or other clients	1. PBAC to obtain records from PLS or FOFLSA 2. List of clients, contact person, telephone numbers	Refer to Suppliers performance evaluation criteria on the AO of Suppliers Accreditation
10	Current capacity to enter into new contract	Current contract with DOH, RHOs and Hospitals Current contract with other government agencies or hospitals and private entities	Check with PLS, RHOS and hospitals and other clients and determine capacity to produce and deliver based on bid requirements

#	Criteria	Requirements	Counterchecks
11	Passed test required	1. Batch certificate for antibiotics 2. Dissolution and/or disintegration test for medicines in tablet or capsule form 3. Suspendibility test for medicines in suspension form 4. Pyrogen test for IV fluids 5. Bioavailabity/ bioequivalence test for medicines under List B Prime 6. Depressant test for streptomycin 7. Neutralizing test for antacids 8. Bioassay for oxytoxin	Countercheck with BFAD
12	Membership to the Association of Drug Industries in the Phil (ADIP); Filipino Drug Association (FIDA) and Chamber of Filipino Drug Manufacturers and Distributors, Inc. (CFDMDI)	Valid Membership Certificate	Check with the associations' lists

8.5.2 DRUG MANUFACTURER WITH DISTRIBUTOR

The requirements for Drug Manufacturer-Distributor also apply to Drug Manufacturers with Distributor including the following additional criteria:

#	Criteria	Requirements	Counterchecks
13	Well-established business relationship between manufacturer and distributor	1. Proof of business relationship for at least 2 yrs 2. Certification from manufacturer indicating company as the official and exclusive distributor in the bidding and area	Check with BFAD, relationship may also be indicated in the CPR
14	Distributor's financial stability	Exclusive Distributor's duly audited financial reports for the last two years (If the bidder selected as the lowest evaluated bid has a networth below total contract price, a credit line from a reputable bank should be required)	Check with signing auditor-accountant. Also check accountant's certificate of registration from PRC or PICPA if doubtful. To be analyzed by FS and FOFLSA for financial capability.

8.5.3 DRUG DISTRIBUTOR WITH AN ACCREDITED MANUFACTURER

The requirements for Drug Manufacturer-Distributor also apply to Drug Distributor with Manufacturer including the following criteria : **Both the Distributor and manufacturer should be accredited.**

#	Criteria	Requirements	Counterchecks
13	Well-established business relationship between drug trader & toll manufacturer	1. Proof of business relationship for at least 2 years 2. Certification from drug trader that company is its exclusive toll manufacturer.	Check with BFAD, relationship may also be indicated in the CPR
14	Manufacturer's financial stability	Manufacturer's duly audited financial reports for the last two years	Check with signing auditor-accountant. Also check accountant's certificate of registration from PRC or PICPA if doubtful. To be analyzed by FS and FOFLSA for financial capability.

8.6 The manufacturer must have a good standing with its clients especially with the DOH. Track record shall be provided by FOFLSA and PLS and the RHOs and the hospitals.

8.7 BFAD shall provide on a monthly basis a list of valid LTO and CPR to PLS , PBAC and TEC at the central office, RHO and DOH hospitals. LTO is issued by BFAD to pharmaceutical establishment which is found to comply with good manufacturing practice. Initially this is valid for one year. Then, all licensed establishments are regularly inspected once or twice every year, the result of which becomes a basis of renewing the LTO for the next two years.

9. ANNUAL PROCUREMENT PLANNING

9.1 All programs are required to plan for the resource requirement of their programs for the succeeding year.

9.2 An annual procurement plan (APP) should not be separately submitted for GOP and foreign funded projects not later than September 15th of the preceding year. Source of funding should be identified though.

9.3 The APP shall be approved by the Undersecretary or head of agency concerned.

9.4 On the 5th day of October of each year, the Undersecretary or head of agency concerned shall submit to PLS (Administrative Division) an annual Drugs and Medicines APP and a tentative bidding schedule for consideration.

9.5 All foreign assisted project shall also follow this schedule. Instead of the Project Management Offices (PMO), the Services/Division/Department shall be responsible for the drug and medicines they want to procure for their programs.

Requirements from the lending agency should be planned and anticipated for completion to coincide with the general schedule.

9.6 Failure to submit requirements on dates stated will forfeit inclusion in the annual schedule.

9.7 All amendments to the drugs and medicines APP and schedule shall have to be approved by the management committees at central office, RHO or hospital.

9.8 The following data items should be indicated and available in the drugs and medicines APP.

- 9.8.1 Type/specification of drugs and medicines to be procured (generic name, dosage strength, dosage form, packaging, etc.)
- 9.8.2 Quantity
- 9.8.3 Quality
- 9.8.4 Unit Cost
- 9.8.5 Name of Program
- 9.8.6 Date of program launching or when requested drugs are needed
- 9.8.7 Schedule of deliveries
- 9.8.8 Distribution list
- 9.8.9 Funding source whether from GOP or PAPs including PPA(Program, Project, Activity)

9.9 Incomplete submission will be automatically returned to the units concerned.

9.10 As early as October of the preceding year, PLS and PMO of foreign funded projects shall have prepared the draft bid documents to be submitted to the PBAC for comments.

0. PROCUREMENT PHASE REQUIREMENTS:

10.1 To initiate procurement, the following must be submitted by end-user Services/Program in its final form to PLS)or Administrative Division, RHO/Hospital). Incomplete submissions based on PLS checklist shall not be accepted and shall be returned automatically to units concerned:

- 10.1.1 Final APP
- 10.1.2 RIV preferably on the first quarter. It must be complete, properly approved and submitted within a scheduled time frame. The RIVs must contain all the required information and must be submitted at least 6 months before the intended use. Programs must consider the duration of the bidding process. The RIV should contain the following: 1)balance on hand, 2) quantity, 3) unit, 4) specification in accordance to the PNDF, 5) current cost estimate based on the last purchase price or the lowest price from at least 3 drugs store chains, and 6) page(s) in APP and PNDF where the particular drug is found.
- 10.1.3 Final special conditions for bidding -- labeling, expiry date, result of stability study for long expiry date, delivery conditions/schedules, distribution list, etc. Also refer to sections II.8, II.14 and II.15.
- 10.1.4 Responsible officers/personnel for the procurement
- 10.1.5 Clearance from the National Drug Committee when there is conflict of

what to buy like insistence for exclusive distributorship. Refer to II.1

10.2 PLS (Administrative Division) shall prepare the draft bid documents for GOP funded drugs and medicines with the assistance of the PMOs for foreign assisted projects. PLS (Administrative Division) and the PMO shall make sure that the bid documents have been reviewed and approved by the PBAC and End-User Services before it is released.

11. MODE OF PROCUREMENT AND BIDDING EVALUATION:

11.1 ALL request shall be procured through public bidding unless another type of procurement method is necessary as prescribed under EO 302 or by the international funding institutions.

11.2 If there is conflict on what to buy or the insistence that a particular drug is the best available for the program and therefore have to buy from an exclusive distributor, clearance from the NDC/NDP should be obtained. Refer to II.1

11.3 Purchase Order of P2 million and above shall be approved by 2 Undersecretaries and the Secretary of Health.

11.4 Contracts for drugs and medicines amounting to P50 M and above shall be submitted to the Office of the President for clearance per memorandum dated August 25, 1998.

11.5 A two-stage bidding is preferred wherein the bidders are required to submit two envelopes

11.5.1 Prequalification documents/Technical Proposal - 3 copies

11.5.2 Sealed financial proposal -3 copies

The PBAC together with the TEC shall open the first envelope and evaluate the proposals based on established criteria. They shall establish which of the bidders are complying or have met the minimum requirements for the bidding. The financial proposal of all the bidders which are found to be complying will be opened and evaluated while the financial proposal of those non-complying bidders will be returned unopened to the respective bidder.

11.9 Preferably, the net worth of the supplier must be equal or more than the contract price. No supplier will be awarded a contract if his declared net worth is below 50% of the total contract price. Credit line from a reputable bank equivalent to the deficiency may be submitted as an additional financial back-up. The Procurement and Logistics Service shall monitor all regional procurements and shall ensure that this provision is followed.

12. PRICE MONITORING:

12.1 BFAD (FDRO) shall submit or provide copies of the price monitoring report from the regular BFAD inspection or price data from at least 3 major drug stores to NDP (RHO PBAC) for consolidation and analysis.

12.2 The price monitoring data from NDP shall be endorsed to the PIC, PBAC, PLS, RHO and hospitals on a monthly or per need basis especially during bidding periods.

12.3 The PBAC with PLS (ARD) and PIC shall publish a price ceiling for each type of drugs or medicines being bidded based on the price monitoring report of NDP(FDRO/MAA).

12.4 BFAD/NDP (FDRO/MAA) shall also maintain a computerized system which could be accessed by the procurement bodies at the central office and the RHO and hospitals.

13. FREQUENCY, SCHEDULE & VENUE OF BIDDING

13.1 For each type of drug or medicines, at least two bidding schedules shall be undertaken every year. Regular bidding for drugs and medicines will be on March and July of each year. Special procurement packages not accommodated or processed in the first two schedules may be scheduled by the PBAC as needed with PLS (Administrative Division) upon approval of the special bidding by EXECOM (MANCOM at the RHO and hospitals) in cases of epidemics, calamity or special projects.

13.2 Bidding will only be scheduled on Mondays and Tuesdays of these months.

13.3 A specific venue (Convention Hall for central office) shall be reserved exclusively for this undertaking on these days and months.

13.4 A contract may have different delivery dates as decided upon by program manager and head of agency concerned based on program plans and pre-planned delivery schedules. This should be indicated in the specific conditions for bidding. The Finance Service (Finance Division) shall be consulted on payment concerns.

14. INSPECTION AND ACCEPTANCE OF DRUGS AND MEDICINES.

14.1 PLS (Supply Section) shall spearhead inspection as soon as goods are delivered

14.2 BFAD/NDP Representative (FDRO) must always be present

14.3 Requesting end-user must always be present. If the Representative of the End-User Service(Section/Division) is absent during scheduled inspection, the goods shall not be inspected and not accepted until the End-User Representative participates in the inspection.

14.4 All drugs including vaccines or biologicals procured by the DOH should have:

14.4.1 Label " Government Property Not For Sale"

14.4.2 Expiry date on the immediate container/package and box container. The expiry date is based on accelerated and/or actual room temperature stability studies conducted for such products. Different products may have different expiry dates since their stability shall depend on product formulation and specific physio-chemical characteristics of drug substance. Locally manufactured drugs can also claim long expiry dates if

the results of their stability studies can support such claim. The expiry date should be at least 18 months at the time of delivery.

14.5 Any conflict among the inspecting and accepting personnel shall be endorsed to the EXECOM (MANCOM) for resolution through the Undersecretary (Division Chief) concerned.

15. DRUG TESTING

15.1 Drugs and medicines subject to testing as stipulated in Title 7, Chapter 1, Articles 17 and 18 of the Government Accounting and Auditing Manual (GAAM), Volume I shall be strictly enforced. Exemption from the above provisions need an official statement from the Commission on Audit when officially requested by the Department of Health for the test may be waived per Section 483.

15.2 All antibiotics are batch certified by BFAD so the DOH need not submit to BFAD for analysis the antibiotics it procures(AO 151 s 1970). All batches produced by local manufacturers or are imported are required to be subjected to BFAD testing and analysis prior to marketing. The DOH should only require the company's LTO, the CPR for specific antibiotic products and batch certificate issued by BFAD. Such batch certification should be verified.

15.3 For all the other products, only the valid, LTO and CPR shall be required by DOH. BFAD shall only conduct spot testing of DOH procured drug products at random during manufacturing or delivery. Manufacturers of products which did not pass the standards and requirements shall be blacklisted from joining the DOH bidding.

15.4 Result of the random testing by BFAD shall be submitted to PLS with in 15 working days.

15.5 If the winning bidder is issued a Notice of Award for a certain drug, BFAD is ordered to monitor said manufacturer and report to PLS and Requesting Service (Division/Program) the result of their visits.

16. SUPPLIERS PERFORMANCE EVALUATION

16.1 To ensure that we only deal with worthy suppliers, FOFLSA or its equivalent at the region/hospital in cooperation with PLS will set up a Suppliers Performance Evaluation Unit (SPEU). PLS with the Regions and hospitals shall maintain a suppliers track record system in support to the SPEU. This will include a mechanism of suspending and even blacklisting erring suppliers. Reference should be made to a separate administrative order on the "Guidelines and Procedures on Accreditation of Government Suppliers of Pharmaceutical Products.".

16.2 Report of quarterly performance shall be submitted to PBAC, TEC, IAU and the OLA and to all RHOs and Hospitals.

16.3 The unit shall maintain a computerized system which can be easily accessed by concerned procurement bodies including the RHOs and hospitals.

17. PAYMENT

17.1 Payment of winning bidder shall not exceed 7 working days upon submission of **complete financial papers** to Finance Service/Division (ANNEX A). A checklist will be provided by Finance and incomplete submission will not be accepted. No additional requirements will be requested unless called for by new auditing and accounting rules.

17.2 A maximum 2 days will be imposed for each clearing or approving officer.

17.3 The approving officer shall designate an alternate signatory when on travel or not in the office for at least two consecutive days.

17.4 A routing slip shall be used to pinpoint bottlenecks

17.5 No follow-up among supplier is allowed.

17.6 Payment of transaction shall be on a first come first serve basis regardless of whether it is funded by GOP or FAPs.

18. DISTRIBUTION AND DELIVERY

18.1 All Requesting Service or Program shall be responsible in scheduling the delivery and distribution of their drugs and medicines. As early as the planning phase, distribution list and delivery schedules should be submitted to PLS (Administrative Division). PLS (Administrative Division) will facilitate the hauling or shipping to the field offices.

18.2 All Services (Program Coordinators) shall keep an inventory record of their drugs and medicines and should be able to account where these drugs were used or distributed. These drugs and medicines should be treated as accountable goods.

18.3 Warehousing is the Procurement and Logistics Service (Administrative Division's) responsibility. End-user service/program/division representative shall however be allowed to have access to the warehouses upon official request.

19. PROCUREMENT INFORMATION CENTER

19.1 The PLS (Administrative Division) with the assistance of the PBAC, Public Information and Health Education Service, General Services Division, Administrative Service and Management Advisory Service (and equivalent offices/personnel at the RHOs and hospitals) shall ensure that the procurement process is transparent

19.2 Besides publishing procurement schedules in newspapers, procurement bulletin boards will be set up in conspicuous places with in the DOH (RHO/Hospital) compound. Likewise these schedules will be broadcast through the internet or will be linked with the electronic bidding being set-up by PS-DBM and COA. PLS (Administrative Division) should also notify drug associations like ADIP, FIDA, CFDMDI.

19.3 A room will be set up to contain various procurement materials for reference of interested parties.

20. RESOLUTION OF CONFLICTS AND QUALITY ASSURANCE

20.1 Conflicts among the Service/Programs, PBAC, TEC and other procurement bodies and PLS shall be submitted in writing to EXECOM (MANCOM) for resolution. Likewise, complaints from suppliers will be submitted to this body.

20.2 A Grievance Committee will be presided by the Chief of Staff (ARD/Asst. head) for this purpose.

20.3 A semestral/annual process of operations audit and performance evaluation of the committees/units and the end-user services at all levels shall be undertaken. This will be led by FOFLSA.

III. FUNCTIONS AND RESPONSIBILITIES
[Equivalent units or individuals should be identified at the RHO and hospital)

1. END-USER SERVICE/PROGRAM

1.1 Prepares the initial Service Annual Procurement Plan (APP) before September 30th of the preceding year in tandem with the budget preparation period; In the preparation, the Services (Divisions/Departments) should take into consideration the RHO annual APP to avoid duplication, over supply and procurement of unnecessary drugs and medicines in the area. As early as August 31st of each preceding year, the RHO should already be preparing their APP for the program. Refer to RHO Standard Procurement System.

1.2 Submits a soft copy and hardcopy (using computerized APP) of requirements to Undersecretary (Division/Department . Chief in RHO/Hospital) concerned for consolidation and preparation of the draft drugs and medicines Annual Procurement Plan. REFER to section II.9

1.3 Upon approval of the budget by DBM and determination of budget ceiling, revises and finalizes APP with item prioritization;

1.4 Ensures completeness and accuracy of specifications by referring to the PNDP and/or NDP;

1.5 Seeks approval from official concerned if APP is amended

1.6 Seeks approval from the NDC/NDP/ Therapeutic Committee for exclusive distributorship and when there is a conflict of what to buy. REFER to II.1 or II.11.6

1.7 Prepares and submits complete RIV, distribution list and certificate of availability of funds and other requirements . Refer to section II.10 for requirements.

1.8 Reviews all bid documents within 2 days

1.9 Participates in the pre-bid, bidding, technical evaluation, inspection and acceptance of goods requested;

1.10 Ensures that the drugs and medicines are delivered and distributed on time to the right beneficiaries

1.11 Approves and signs procurement and related financial documents as required per administrative order on delegation of authority.

1.12 Monitors and accounts for procured and distributed drugs
1.13 Monitors sub-allotted funds

2. OFFICE OF THE UNDERSECRETARY

2.1 Consolidates and approves the various Service APPs and amendments as may be necessary;
2.2 Submits the Office drugs and medicines APP to PLS (Administrative Division)
2.3 Prepares with the Services under its jurisdiction an annual schedule for bidding for drugs and medicines to be submitted to PLS and PBAC
2.4 Approves manner of procurement as stated above in page 1.
2.5 Approves mode of procurement under direct contracting and negotiated procurement through the EXECOM (MANCOM) in cases of emergency or when projects/activities cannot be delayed.
2.6 Approves and signs procurement documents and vouchers as stipulated in the delegation of authority or subsequent amendment or issuance thereof.
2.7 Approves Notice of Award as recommended by PBAC per EO 302 and per delegation of authority
2.8 Supervises and assumes accountability for all the all committees and units under its jurisdiction as stipulated Section I of this AO.
2.9 Evaluates the performance of these committees/units and give commendation or awards if necessary.
2.10 Supervises all Project Management Offices of all foreign assisted projects under its Office.

3. BUREAU OF LICENSING AND REGULATIONS

3.1 Creates a unit to spearhead the suppliers accreditation of pharmaceutical products in the DOH.
3.2 Regularly reviews annual accreditation criteria with experts and/or standard setting services and improves these based on the requirements of the end-users and government rules and regulations with the various procurement committees and current industry and technology standards;
3.3 Categorizes suppliers according to capitalization, net worth and other defined criteria such as product/services provided, working capital, facilities and equipment, track record and capacity to enter into contract;
3.4 Conducts evaluation of suppliers based on documents required and submitted, and track record from PLS or the inputs from the suppliers performance evaluation unit of FOFLSA ;
3.5 Conducts unannounced inspections of suppliers for purposes of accreditation only;
3.6 Prepares and issues a Certificate of Accreditation to qualified DOH suppliers through the Undersecretary of OSR.;
3.7 Operates and maintains a computer-based Suppliers Accreditation System to facilitate updating and access of information on DOH suppliers;
3.8 Publishes quarterly the list of accredited suppliers; and disseminates list of accredited suppliers to PBAC, PLS, RHOs and retained hospitals.

4. BUREAU OF FOOD AND DRUGS/NATIONAL DRUG POLICY

4.1 Permanently serves as the DOH Price Monitoring Unit for Drugs and Medicines in cooperation with the National Drug Policy;

4.2 Regularly publishes a price monitoring list from the regular BFAD inspection of pharmacies and/or from at least 3 major drug stores and disseminate to PLS, PBAC, RHO and Retained hospital through the Undersecretary of OSR

4.3 Operates a computer-based Price Monitoring System to facilitate updating and access of information on prices of goods through the NDP;

4.4 Takes active part in the procurement process as member of the TEC, IAU and accreditation committee.

4.5 Supplies the PLS and the PBAC of the central office, RHOs, hospitals on a regular basis list of suppliers with valid LTO and CPR, including a copy of the LTO and CPR when necessary and antibiotics batch certification

4.6 Assists PBAC and PLS/Administrative Division in establishing price ceiling

4.7 Undertakes the testing required for drugs and medicines when D&M are manufactured and delivered

4.8 Regularly monitors the winning bidder during the manufacturing stage

5. FINANCIAL OPERATIONS AND FRONTLINE SERVICES AUDIT

5.1 Observes, assesses and makes a report the process undertaken during the pre-bidding and bidding conferences and other meetings of the PBAC, if these are within government rules and regulations or funding agency requirements, and suggest improvements

5.2 Analyzes financial statements submitted by the suppliers and establishes net worth and categorization of suppliers by financial capability together with FS

5.3 Creates a unit to undertake a suppliers performance evaluation and submits report to the Suppliers and Service Contractors Accreditation Unit, PBAC RHOs and hospitals

5.4 Recommends to the Secretary of Health poor performing or erring suppliers for suspension and blacklisting and even debarment from future bidding of the DOH

5.5 Prepares and submits a historical report of public bidding to EXECOM (MANCOM)

5.6 Monitor or audit compliance to this order at the central office, RHOs, and hospitals.

6. OFFICE FOR LEGAL AFFAIRS

6.1 Acts as the Executive Officer and Secretary of the PBAC

6.2 Provides legal advise during the pre-bid, bidding and deliberation of bids;

6.3 Creates a procurement contract unit who will then be assigned to prepare pro-forma or standard contracts

6.4 Reviews all contracts as a result of the bidding or negotiations with PLS(Administrative Division);

6.5 Ensures that all procurement contracts are reviewed within 10 working days

6.6 Whenever necessary, provides legal services in cases of complaints.

7. FINANCE SERVICE

7.1 Informs Offices/Services of the monthly status of their budget, particularly for drugs and medicines;

7.2 Issues Certificate of Availability of Funds before any procurement transactions.

7.3 Prepares all the necessary financial documents needed for procurement as may be required (e.g. opening of letter of credit); and

7.4 Facilitates payment of suppliers in coordination with the end-user(s).

7.5 Operates and maintains the computer-based financial management information system to facilitate updating, recording and reporting of financial transactions

7.6 Analyzes financial statement submitted by the suppliers. Establishes net worth and categories of suppliers by financial capability together with FOFLSA

7.7 Monitors utilization of sub-allotments to RHOs and hospitals and payments to various procurement agents.

8. PROJECT MANAGEMENT OFFICE OF FOREIGN ASSISTED PROJECTS

8.1 Coordinates with end-user services available procurement packages to be funded by the project

8.2 Prepares bid documents together with the end-user services and PLS

8.3 Facilitates concurrence, approval and resolution of issues for procurement transactions by the lending agency.

9. PREQUALIFICATION, BIDS AND AWARDS COMMITTEE

9.1 Establishes price ceiling of drugs with BFAD/NDP and PLS

9.2 If procurement is through public bidding, the PBAC undertakes the following:

9.2.1 Sets the category of suppliers to qualify for each item to be bidded with active participation from the Service and TEC;

9.2.2 Finalizes the prequalification and bidding criteria and include this if any to the prepared Bid Documents.

9.2.3 Ensures that the specifications are in accordance with the approved RIV;

9.2.4 Approves bid advertisement;

9.2.5 Conducts Pre-bid Conference on the scheduled date. If there is anything discussed in the Pre-bid Conference that is agreed upon by both PBAC

and Suppliers, issue the Bid Bulletin prior to the bidding date, and inform those who were not able to attend the Pre-bid Conference; and

9.2.6 Conducts public bidding for bulk purchases, negotiate purchase or process canvass for Central Office goods and services as the case may be on scheduled time, date and place.

9.3 Reviews documents and selects/establishes bidders who have met minimum requirements

9.4 Endorses bidding documents to Technical Evaluation Committee (TEC) for pre-qualification and technical evaluation;

9.5 Reviews the pre-qualification results and Technical Evaluation Report with TEC

9.6 Opens financial proposal of complying bidders

9.7 Recommends approval of lowest evaluated bidder to Undersecretary concerned/(RD) and/or Secretary of Health depending on the amount of transaction involved; and

9.8 Endorses Notice of Award to PLS for issuance.

10. PBAC SECRETARIAT

10.1 Prepares draft bidding schedules in coordination with PBAC and PLS (Supply Section, Administrative Division);

10.2 Coordinates with PLS (Administrative Division) bidding dates and publications;

10.3 Prepares pre-bidding minutes and bid bulletin, and submits approved bid bulletin to PLS/Administrative Division for issuance;

10.4 Assists the PLS Secretariat during bidding in accepting bid proposals for stamping and numbering; entering of bid prices in the Bid Abstract sheet upon announcement of the PBAC Chairperson;

10.5 Prepares and files bid minutes;

10.6 Keeps financial proposals until opening date

10.7 Endorses the bid documents to the TEC upon the instruction of the PBAC;

10.8 Prepares minutes of meetings and resolutions during the deliberations;

10.9 Prepares Notice of Award for approval then endorses to PLS/Administrative Division for issuance. This follows the Administrative Order on the Delegation of Authority;

10.10 Returns all bidding documents to PLS for safekeeping;

10.11 Provides clerical and custodial support to the PBAC.

11. TECHNICAL EVALUATION COMMITTEE

11.1 Receives and checks for completeness of bid documents and make a report to PBAC;

11.2 Reviews the prequalification, technical evaluation and acceptance criteria and submits to PBAC for approval;

11.3 Prequalifies bidders with PBAC

11.4 Reviews technical proposals based on approved technical evaluation criteria; and

11.5 Prepares, submits and presents Technical Evaluation Report to PBAC for final decision.

12 . PROCUREMENT AND LOGISTICS SERVICE

12.1 Consolidates the APP of the various major Offices/Services (Division) into one DOH (RHO)APP ; Refer to II.9.

12.2 Checks RIVs for completeness and other required documents and returns immediately to requesting end-user if incomplete. Refer to II.10

12.3 Consolidates various Offices (Division) drugs and medicines APPs/RIVs

12.4 Prepares draft and final bid documents as soon as Office(RHO) drugs and Medicines APP is submitted and endorsed to PBAC

12.5 Recommends to PBAC mode of procurement except when mode is direct contracting or negotiated purchase other than 2 bid failures. Refer to II.11

12.6 Assists the PBAC, and BFAD/NDP (FDRO/MAA) in the establishment of price ceiling

12.7 Schedules bidding dates based on the DOH APP with Undersecretary concerned and PBAC. Refer to II.19

12.8 Prepares and publishes bidding in coordination with the PBAC Secretariat and PIC. Refer to II.19;

12.9 Prepares venue for bidding and other supplies and materials needed

12.10 Notifies all concerned of the procurement activities in writing at least two weeks prior to the actual date and by phone two days before a procurement activity. Refer to II.4

12.11 Provides assistance in the Pre-bid Conference. It shall undertake the following: prepares the venue, notify members of the PBAC including non-voting members and end-users; gets attendance and issues bid bulletin prepared by the PBAC Secretariat as approved by the PBAC Chairperson;

12.12 During the bidding, it shall undertake the following: accepts bid proposals for stamping and numbering; gets attendance of all those present; checks submitted bid proposals against the suppliers'distribution list and the list of required documents; secures the bidders bond; and prepares the abstract of bids with the PBAC Secretariat;

12.13 Endorses copies of bid documents to COA and PBAC and posts the third copy;

12.14 Releases Notice of Award to winning bidder when approved by the PBAC;

12.15 Informs the awardee(s) on the amount of performance bond and accepts submission of such bond;

12.16 Prepares and processes Purchase Orders and contracts for the signature of respective officials;

12.17 Schedules delivery with end-user Service and prepare Notice of Delivery

12.18 Establishes an inspection and acceptance unit in cooperation with BFAD (FDRO)and the end-user Service. Refer to II.14

12.19 Conducts technical Inspection and Acceptance with BFAD and end-user Service concerned for D&M delivered at the Central Office based on the PO/contract. This should be done within three working days upon delivery of goods at the warehouse;

12.20 Prepares and submits an inspection report and certificate of sampling if applicable within three working days from date of inspection.

12.21 Submits a report to PBAC a copy a outstanding contracts of suppliers to determine their capability to handle multiple contracts;

12.22 Maintains a suppliers track record system and gives report to FOFLSA (ARD), Accreditation Unit and PBAC and TEC. Refer to Section II.16

12.23 Prepares disbursement voucher for payment and attaches all required supporting documents (Annex A)

12.24 Ensures that the drugs and medicines are properly stored in the warehouse. Refer to II.18

12.25 Distributes goods with end-user Services based on list given by Services;

12.26 Monitors status of shipment

12.27 Prepares and submits monthly report of goods received and issued based on delivery receipts to FS and COA. The reports must be by fund source.

12.28 Operates and maintains a computerized logistics management information system (LMIS) such as APP, distribution, inventory and warehousing system

12.29 Establishes a Procurement Information Center. Refer to II.19

12.30 Monitors regional procurement and suggests improvements.

13. MANAGEMENT ADVISORY SERVICE

13.1 Assists in the regular evaluation of the system and process and revising these guidelines as needed.

13.2 Provides technical assistance in setting up a computerized LMIS.

13.3 Provides support in broadcasting procurement schedules in the internet.

All other issuances contrary to this are rescinded. For goods other than drugs and medicines. AO 14-B s. 1997 remains in effect until a new system is implemented.

For compliance.

7/12/99

ALBERTO G. ROMUALDEZ, JR., M.D.
Secretary of Health