[ADMINISTRATIVE ORDER NO. 2018-00020, July 30, 2018]

AMENDMENT TO ADMINISTRATIVE ORDER (AO) NO. 2016- 0009 - REVISED IMPLEMENTING GUIDELINES ON ELECTRONIC DRUG PRICE MONITORING SYSTEM (EDPMS)

Adopted: 24 July 2018 Date Filed: 30 July 2018

I. RATIONALE

In 2008, Republic Act (RA) No. 9502, otherwise known as the Universally Accessible Cheaper and Quality Medicines Act was enacted mandating the Secretary of Health to establish an electronic price monitoring and regulation system for drugs and medicines. In line with this directive, the Department of Health piloted the Electronic Essential Drug Price Monitoring System (e-EDPMS) through AO No. 2008-0014.

After pilot implementation of the system and following several consultations with the end-users and stakeholders, the e-EDPMS was simplified to make it

More responsive to the needs of users on September 6, 2011, the DOH issued AO 2011-0012 or the Electronic Drug Price Monitoring System (EDPMS) Version 2.0 to was issued through AO 2011-0012 to expand the scope of implementation to cover all drug establishments and outlets, establish guidelines on data validation, analysis, reports generation and dissemination, monitoring and evaluation, and strengthen and provide more coherent roles and responsibilities of the different agencies and stakeholders involved in the implementation of the system.

In the course of implementing AO No. 2011-0012, issues and regarding the difficulty of uploading data into the system were raised resulting in a low turn-out of data collection. The most recent information showed that only an average of 25% of drug establishments and outlets are reporting to the system before the moratorium was issued on July 2, 2012. Complaints vary from inaccessibility of the website, difficulty of sending data to the server, unavailability of internet connection in far flung areas and lack of training of IT personnel.

The primary aim of the EDPMS is to address the information asymmetry in medicine prices and to empower patients and consumers in exercising intelligent choices when purchasing medicines from both the public and private retail outlets. The EDPMS shall be used likewise as a vital reference of the DOH in formulating pricing policies for essential medicines to ensure the affordability and availability of essential medicines in the market.

It is in the above light, that this revised implementing guideline is issued to improve

the system and make it more efficient and effective, such that data gathering and data analysis become more relevant and manageable.

II. OBJECTIVES

To set the guidelines for a more effective and efficient implementation of EDPMS.

III. SCOPE

This Order applies to all bureaus in the DOH Central Offices, Attached Agencies, Regional Offices, Local Government Units, Government and Private Health Facilities, drug establishments and drug outlets and other agency data beneficiaries subject to the rules of compliance provided below.

IV. DEFINITION OF TERMS

For purposes of this Order, the following terms are defined as follows:

- A. **Drug Distributor Exporter** refers to any establishment that exports raw materials, active ingredients and finished products for distribution to other drug establishments outside the country.
- B. **Drug Distributor Importer** refers to any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed drug establishment.
- C. **Drug Distributor Wholesaler** refers to any establishment that procures raw materials, active ingredients and/or finished products from a local FDA- licensed drug establishment for local distribution on wholesale basis.
- D. **Drug Establishment** refers to either sole proprietorship, partnership, corporation, institution, association or organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of drug products including the facilities and installations needed for its activities.
- E. **Drug Outlets** refer to Drugstores, Pharmacies or Botica, including Hospital Pharmacy/Dispensary, where registered drugs, chemical products, active principles, proprietary medicines or a pharmaceutical specialties and dental medicinal, galenical or veterinary preparations are compounded and/or dispensed.
- F. Electronic Drug Price Monitoring System (EDPMS) refers to a computer- based solution with the functionalities to capture, process, store and generate reports on essential drug prices from drug companies, establishments and outlets. G. Erroneous Submission of Data refers to incomplete and wrong or incorrect data submitted/uploaded to the EDPMS. H. Government Mediated Access Price (GMAP) refers to voluntary price reduction of selected drugs and

medicines pursuant to Resolution No. 2009- 001 of the Advisory Council for Price Regulation.

- I. **Manufacturer** refers to any establishment engaged in any or all operations involved in the production of drug products including preparatory processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution; provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A Drug Manufacturer can distribute and/or export in wholesale its own drug products and import raw materials for its own production.
- J. **Manufacturer Trader** refers to any establishment which is a registered owner of a drug product and the formulation and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures but subcontracts the manufactures of such products to a licensed manufacturer.
- K. **Maximum Drug Retail Price (MDRP)** refers to the ceiling prices imposed for drugs and medicines sold in all retail outlets, whether public or private, pursuant to Executive Order No. 821 (Prescribing the Maximum Retail Price for selected drugs and medicines that addresses diseases that account for the leading causes of morbidity and mortality).

V. GENERAL GUIDELINES

- A. The medicines to be uploaded into the EDPMS are those selected to address the leading causes of mortality and morbidity in the country.
- B. The list of medicines required to be uploaded in the EDPMS are the medicines listed in the current Philippine National Formulary (PNF) and the PNF for and the Primary Health Care that the facility carries. These medicines shall include the drugs listed under the DOH mandatory and voluntary price reduction scheme (i.e. MRP & GMAP).
- C. The EDPMS shall provide the essential medicines price information to patients and consumers to enable them to exercise informed choice when purchasing medicines from public and private retail outlets.
- D. The EDPMS shall also provide the price information which the government shall use in developing pricing policies for medicines and in guiding the design program and health benefit packages of the DOH and the PhilHealth, respectively.
- E. Data uploaded into the system shall be analyzed and randomly validated on a regular basis (quarterly). F. Partnerships with research institutions, the academe and other pertinent agencies and institutions shall be forged for third party/external validation of the EDPMS data and analysis.

G. Blacklisted status due to consistent non-compliance with the uploading requirement to the EDPMS shall not exceed to one (1) year. Blacklisted status will be lifted upon compliance.

VI. SPECIFIC GUIDELINES

A. UPLOADING

1. A Drug outlet having only one (1) branch shall upload through EDPMS their selling prices and inventory once a year according to the following geographical clusters:

MetroJanuary

Luzon - AprilVisayas - July

• Mindanao - October

- 2. **A Drug outlet having two (2) or more** branches shall upload through the EDPMS their selling prices and inventory on a quarterly basis.
- 3. **A Drug outlet in hospitals** in both public and private shall upload through the EDPMS their selling prices to patients and inventory on a quarterly basis. It is understood that medicine prices are consistently applied for in-patient and out-patient care.

4. Drug establishments

- a. Manufacturers and Manufacturer Traders shall upload through the EDPMS their selling price, based on the largest volume on a quarterly basis. Toll Manufacturers are exempted to upload because they only process raw materials or semi-finished goods for another company.
- b. *Distributors, Importers, Exporter and Wholesalers* shall upload through the EDPMS their purchase price, selling price and inventory data on a quarterly basis.

Data to be uploaded to the EDPMS by type of drug establishments/facilities are as follows:

Type of Establishment (Facility)	Acquisition Price	Selling Price	Inventory	Month of Uploading
Drug Establishment				
Drug Manufacturers	X	√	X	Quarterly
 Drug Manufact urer Traders 	Х	√	Х	Quarterly
Distributor				

- Importer - Exporter - Wholesaler	√ √ √	√ √ √	√ √ √	Quarterly Quarterly Quarterly
			\checkmark	
Dru g Outl ets				
 Hospital (government and private) 	Х	√	√	Quarterly
 Drug outlet with two (2) or more branches 	X	√	√	Quarterly
 Drug outlet with only one (1) branch Clustering 	Х	√	√	Annual
- Metro Manila - Luzon - Visayas - Mindanao				January April July October

Note: The data to be uploaded shall be the latest transaction per item that is recorded during the month before the uploading month. (Example: Last transaction day of months of December, March, June and September.)

Months for quarterly uploading: January, April, July and October.

- 5. Certificate of Compliance to the EDPMS shall be a requirement to all drugs establishments who wish to participate in all government tendering activities for drugs and medicines.
- 6. Price data made available to consumers and the public shall be confined to the final selling prices of medicines in drug chains and retail outlets.

B. LEVEL AND PERMISSION RIGHTS OF USERS

- 1. Only the Secretary of Health and/or his designated officials/employees and the Pharmaceutical Division shall have full unrestricted access to the EDPMS system its price monitoring functions.
- 2. The PD shall define the users who are authorized to use the system, define access level and permission rights, review and approve request to access the system and/or data.
- 3. The PD shall assign and issue user names and passwords unique to each drug establishments and outlets that are going to use the system.
- 4. The PD shall grant appropriate access levels and rights to the following: