# [ FDA Circular No. 2015-007, April 10, 2015 ]

## RULES AND REGULATIONS ON THE LICENSING OF HOSPITALS AND OTHER HEALTH FACILITIES INVOLVED IN THE MANUFACTURE OF MEDICAL GASES

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### I. BACKGROUND/RATIONALE

Section 15, Article II of the 1987 Philippine Constitution declares it a policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Further, Section 11 of Article XIII mandates the State to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost.

Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations, empowers FDA to develop and issue policies, standards, regulations, and guidelines that would cover establishments, facilities and health products, including drug products.

In Republic Act No. 9502 (Universally Accessible Cheaper and Quality Medicines Act of 2008), "Drugs and medicines" are referred to as any article recognized in the current official United States Pharmacopeia-National Formulary (USP-NF) and other specified national compendium or any supplement to any of them, which is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

Oxygen, Nitrous Oxide, Carbon Dioxide, and other medical gases recognized in different pharmacopeias have diverse indications for use and are therefore classified as drugs under the regulatory jurisdiction of FDA.

Presently, manufacturers of medical oxygen in cylinder tanks are required to be licensed as drug manufacturers. Their products are also required to be registered with FDA.

With the recent increase in the number of hospitals and other health facilities setting-up their own medical gas generating machines and subsequent engagement in the manufacture of medical gas both for inpatient use and other consumers, FDA, as the drug regulatory authority of the Philippines responsible for ensuring the safety, efficacy, and quality of drug products, hereby promulgates the following rules and regulations on the licensing of these establishments. This Circular is issued following the provisions of Administrative Order No. 2014-0034 (Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture,

Conduct of Clinical trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations), dated 13 October 2014.

## II. OBJECTIVES

The objective of this Circular is to promulgate the rules and regulations on the licensing of hospitals and other health facilities involved in the manufacture of medical gases as drug manufacturers.

## III. SCOPE

These rules and regulations shall apply to all government and private hospitals and other health facilities engaged in the manufacture of medical gases. For the purpose of this Circular, "medical gases" shall refer to any gas or mixture of gases intended for administration to patients for anesthetic, therapeutic, diagnostic or prophylactic purposes, which may be manufactured in a liquefied, non-liquefied, or cryogenic state and administered as a gas. These gases may be stored in cylinders, pressurized storage tanks, or in low pressure collecting tanks.

## IV. IMPLEMENTING DETAILS

A. *Establishments Required Licensing*

All government and private hospitals and other health facilities engaged in the manufacture of medical gases are required to secure a License to Operate (LTO) as drug manufacturer. For the purpose of this Circular, a "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.

An LTD is required for abovementioned establishments regardless of the following:

1) Method of medical gas manufacturing (e.g., concentrator, chemical synthesis, purifier)
2) Scale of manufacturing (e.g., small, medium, large)
3) Mode of gas delivery (e.g., from cylinders, from a medical gas pipeline system)
4) End users of the manufactured medical gas (e.g., inpatients of hospitals and other health facilities, other consumers)
5) Type of ownership (e.g., Department of Health (DOH)-retained, Local Government Unit (LGU)-owned, privately-owned]

B. *Documentary Requirements*

1) Application Form

   A completely filled-out and notarized application form signed by the pharmacist and owner/authorized representative must be submitted.

2) Proof of Business Name Registration

A valid proof of business name registration must be submitted:

(a) For single proprietorship - Certificate of Business Registration issued by the Department of Trade and Industry (DTI)
(b) For corporation, partnership and other juridical person – Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation
(c) For cooperative - Certificate of Registration issued by the Cooperative Development Authority and the approved by-laws
(d) For government-owned or controlled corporation - the law highlighting the provision creating such establishment

The proof of business name registration must specify the exact and complete address, e.g. unit number, floor, building, lot, block, phase, street, barangay, city/ municipality, province, where applicable.

3) Credentials of the Pharmacist-in-Charge

The credentials of the identified pharmacist-in-charge must be submitted, which include:

(a) Valid Professional Regulation Commission (PRC) ID
(b) Certificate of Attendance to appropriate FDA Licensing Seminar
(c) Resignation letter of the pharmacist from previous employer (if previously employed)

The other qualified personnel shall be listed, which include the (1) hospital engineer or equally qualified person responsible for overseeing the operations of the manufacturing facility and (2) personnel responsible for maintenance. The credentials will not be submitted during application but may be verified during inspection.

4) Risk Management Plan

A general Risk Management Plan (RMP) for the establishment must be submitted. The RMP shall contain details on how to identify, characterize, prevent or minimize risks relating to the medical gas they engage in. These shall include pharmacovigilance activities and interventions of the establishment to manage the risks.

5) Location Plan

A sketch of the location of the establishment must be submitted which shall be used for inspection purposes. This sketch must indicate clear directions with identified landmarks to locate the establishment.

In addition, the Global Positioning System (GPS) Coordinates in decimal degrees (DD) [Latitude and Longitude] must be indicated in the submission.

6) Site Master File

The Site Master File (SMF) must be submitted, in accordance with the latest edition of the Pharmaceutical Inspection Cooperation Scheme