



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

October 27, 2014

ADMINISTRATIVE ORDER
No. 2014 - 0036 (VERSION 2)

SUBJECT: Supplemental guidelines to Administrative Order 2012-0012 to Strengthen the Role of the Bureau of Health Facilities and Services (BHFS) and DOH Regional Offices (ROS) in Licensing of Hospitals and Other Health Facilities

I. Background and Rationale

Republic Act 4226 otherwise known as the Hospital Licensure Act mandated the Bureau of Medical Services, now known as the Bureau of Health Facilities and Services (BHFS), to act as the licensing agency of the country. This has been enforced through the implementation of the Executive Order No. 102, which redirects the functions and operations of the Department of Health and DOH Administrative Order No. 147 s. 2004, entitled Amending Administrative Order No. 70A, series 2002 re: Revised Rules and Regulations Governing The Registration, Licensure and Operation of Hospitals and Other Health Facilities in the Philippines, which state that the DOH, through BHFS, shall be the principal agency in ensuring equity, access and quality of health care services through policy formation, standards development and regulations.

With the increasing number of hospitals, and subsequently other health facilities as well, being regulated, regulatory functions have been decentralized to the DOH Regional Offices (DOH-ROS), formerly Centers for Health Development (CHDs), through its Regulation, Licensing and Enforcement Division (RLED). Based on Administrative Order No. 2007-0021, which sets the standards for the Harmonization and Streamlining of the Licensure Systems (One— Stop-Shop System) for Hospitals, Section V.B enlists the procedural guidelines for the decentralization of the regulatory functions to the DOH-ROS. Furthermore, Section V.B.1.d clearly states that the BHFS, along with the Bureau of Health Devices and Technology (BHDT) and Bureau of Food and Drugs (BFAD), now Food and Drugs Administration (FDA), shall exercise oversight, supervisory and monitoring functions over the Regional Offices with regards to the regulation of hospitals, their ancillary and other facilities. Furthermore, Administrative Order No. 2012-0012, entitled Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines has already set the standards of the new classification of hospitals and other health facilities. In this policy, it was also stated that the BHFS and Regional Offices will work closely and reiterated the division of labor in terms of licensing of health facilities.

Since 2012, the Department of Health has been ISO certified by the Certification International

Philippines, Inc. (CIPI) for the Health Systems Administration, which includes Health Regulation. This policy adheres to the idea of continuous quality improvement in the sector of health regulation, through activities that would make our requirements be more client- responsive in the course of enforcement of minimum standards for patient safety.

Hence, this order is hereby created to strengthen the oversight functions of BHFS to ensure synchronization of the processes from the Central Office to the Regional Offices, through their respective RLEDs.

II. Objectives

1. To strengthen the oversight function of the BHFS in ensuring equity, access and quality of health care services in the regions.
2. To enforce harmonization of licensing and accreditation processes and procedures in the Central and Regional Offices of the Department.

III. Scope and Coverage

This policy covers the Bureau of Health Facilities and Services, Food and Drug Administration, all Regulatory, Licensing and Enforcement Division (RLED) from the Seventeen (17) DOH Regional Offices, including ARMM, and all concerned.

IV. Definition of Terms and Acronyms

1. BHFS — Bureau of Health Facilities and Services
2. COA — Certificate of Accreditation
3. CON — Certificate of Need
4. DOH-ROS — Department of Health Regional Offices
5. FDA - Food and Drug Administration
6. HMO — Health Maintenance Organizations
7. LTO # License to Operate
8. PTC — Permit to Construct
9. RLED — Regulatory, Licensing, and Enforcement Division of the DOH Regional Offices

V. Roles and Responsibilities

In order to clarify the roles and responsibilities in accordance to the provisions of existing licensing issuances, the following are reiterated:

A. BHFS

1. To set standards for regulation of health facilities and services
2. To create/modify inspection and monitoring tools from time to time
3. To disseminate regulatory policies, standards and forms for information and guidelines of the

Regional Offices

4. To provide consultation and technical assistance to stakeholders, including regulatory officers from the DOH—ROS in regulation of health facilities and services

To issue the following:

a. Permit to Construct (PTC)

1. Ambulatory Surgical Clinic
2. Birthing Home
3. Dialysis Clinics
4. Drug Testing Laboratory
5. Drug Abuse Treatment and Rehabilitation Center
6. Hospitals, including Infirmary
7. Medical Facility for Overseas Workers and Seafarer
8. Psychiatric Facility

b. License to Operate (LTD)

1. Hospitals, including other health facilities under the One-Stop-Shop system in AO 2007—0021

a. Initial for Level 1

b. Initial and Renewal for Levels 2 and 3

2. Non-hospital based facilities (facilities outside the hospital premises)

a. Ambulatory Surgical Clinic

b. Blood Bank

c. Blood Center

d. Dialysis Center

e. Psychiatric Facility (initial)

c. Certificate of Accreditation (COA)

1. Drug Testing Laboratory
2. Drug Abuse Treatment and Rehabilitation Center
3. Human Stem Cell/ Cellular Therapy Facilities
4. Kidney Transplant Units
5. Laboratory for Drinking Water Analysis (initial)
6. Medical Facility for Overseas Workers and Seafarers
7. Newborn Screening Facilities
- d. Clearance to Operate for HMOs
- e. Certificate of Registration for Special Clinical Laboratories
- f. Permit for Remote Collection of Drug Testing Specimen
- g. Certification as Registered Health Facility
6. To conduct unannounced monitoring visits to regulated health facilities
7. To promptly respond to complaints of clients to the health facilities they regulate
8. To closely coordinate with FDA to ensure adherence of processes as stated in AO 2007-0021 or the One-Stop—Shop System for Licensing of Hospitals
9. To visit the RLEDs in the Regional Offices to evaluate the adherence of the division in the licensing processes and procedures. See Annex A of this order for the specific guidelines of the visit.
10. To publish annual report on the updated list of hospitals and other health facilities in the Philippines, sorted according to Regional distribution with the following information: name, location, bed capacity (for hospitals), license number and validity

B. RLED/DOH-ROs:

1. To issue the following:
 - a. Certificate of Need (CON) for Hospitals

b. Permit to Construct of Health Facilities Enhancement Program (HFEP) Projects

c. License to Operate

1. Birthing Home

2. Clinical Laboratory, except Laboratories in Ambulatory Surgical Clinics, Dialysis Centers, OFW Clinics, Level 2, Level 3 and Specialty Hospitals

3. Dental Laboratories

4. Level 1 Hospital (renewal)

5. Infirmary

6. Psychiatric Facility (renewal)

d. Authority to Operate Blood Collection Unit and Blood Station e. Certificate of Accreditation

1. Private School Dental Clinics

2. Occupational establishments dental clinics

3. Laboratory for Drinking Water Analysis (renewal)

2. To furnish the BHFS a copy of the CON Evaluation Tool and other Supporting documents immediately after the CON application has been approved or disapproved

3. To provide the BHFS a copy of the Summary of Evaluation of hospitals inspected for issuance of initial LTO

4. To submit the following reports to BHFS, using the matrix provided by the Bureau:

a. Annual list of Licensed Health Facilities, not later than January 15 of the following year, namely:

1. Birthing Home

2. Clinical Laboratory

3. Blood Service Facilities

4. Laboratory for Drinking Water Analysis

5. Dental Laboratories

6. Infirmary

7. Level 1 Hospitals

8. Psychiatric Care Facilities

b. Semi-annual summary of violations stating, among others, the name of the health facility, locations, its violation and the course of action taken

c. Quarterly report on the number of PTCs issued not later than the 15th day of the following month

d. Quarterly status report of the initial applications not later than the 15th day of the following month

e. Quarterly report on Suspension/Revocation/Cease and Desist Order issued on the aforementioned facilities not later than the 15th day of the following month

5. To endorse to the BHFS any application submitted to their office not within their scope

6. To conduct unannounced monitoring visits to regulated health facilities

7. To promptly respond to complaints of clients to the health facilities they regulate

8. To closely coordinate with FDA, through their Food and Drug Regulatory Officers, to ensure adherence of processes as stated in AO 2007-0021 or the One-Stop—Shop System for Licensing of Hospitals

VI. Repealing Clause

All previous issuances which are inconsistent with the provisions of this Order are hereby repealed, amended or modified accordingly.

VII. Effectivity This Order shall take effect immediately.



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