

RE-CENTRALIZATION OF THE ISSUANCES OF PERMIT TO CONSTRUCT (PTC) FOR ALL LEVELS OF HOSPITALS, LICENSE TO OPERATE (LTO) FOR ALL NEW HOSPITALS AND RENEWAL OF LTO FOR LEVELS THREE (...)

DOH ADMINISTRATIVE ORDER NO. 2010 - 0035, December 14, 2010

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I. BACKGROUND

The primary policy directives under DOH Administrative Order No. 2007-0021 dated June 6, 2007 entitled “Harmonization and Streamlining of the Licensure System for Hospitals,” were the following: 1) Establishment of One-Stop Shop Licensure System for Hospitals; and 2) Decentralization of the licensing process to the CHDs. Under the second primary policy directive, the licensing process for hospitals, both for initial License To Operate of Level 3 and Level 4 hospitals, including the issuance of the Permit To Construct, shall be decentralized to the CHDs. Based on the said Order, the CHDs assumed the regulatory functions last January 1, 2008.

Before the decentralization of the licensing process to the CHDs, the aforementioned regulatory functions specifically the evaluation for Permit To Construct (PTC) and the License To Operate (LTO) of Level 3 and Level 4 hospitals were both essentially undertaken by the Bureau of Health Facilities and Services (BHFS) of the DOH-CO, as originally mandated by and pursuant to Republic Act No. 4226 otherwise known as the Hospital Licensure Act of 1965 and its accompanying administrative issuances.

After two and a half years of implementation, the current management of the DOH-CO has decided to re-centralize the licensing and regulatory functions of the CHDs pertaining to all hospital DOH-PTC evaluations, issuance of LTO for all new hospitals and issuance of renewal of LTO for Level 3 and Level 4 hospitals back to the jurisdiction of the BHFS for the following reasons:

- a) First, the BHFS is conducting a thorough review of the criteria on Certificate of Need (CON) to establish a new general hospital as detailed under Department Circular No. 2010 – 0141. With the suspension of Certificate of Need (CON) and its related issuances, the BHFS shall map out all kinds of services being provided by every hospital particularly level 3 and level 4 hospitals;
- b) Second, decentralization is anchored on the premise that the DOH rationalization plan shall address the requisite number of personnel complement in the different regulatory offices and the CHDs. Yet, after two and a half (2 ½) years of decentralization, an approved rationalized standard staffing requirement is not evident.
- c) Third, on March 23, 2010, the BHFS, in one of its regulatory officers’ dialogue, conducted a rapid survey of the existing CHD plantilla position which revealed inadequate number of technical staff among the current members of the Licensing, Regulatory and Enforcement Units of the CHDs nationwide;
- d) Last but not the least, the DOH through the BHFS by virtue of Republic Act No. 4226 or the Hospital Licensure Act of 1965 and pursuant to its subsequent administrative issuances, is the authorized regulatory body to undertake PTC and LTO applications.

In dealing with the situations above, the DOH-CO has agreed to re-centralize the licensing and regulatory functions of the CHDs pertaining to all hospital DOH-PTC evaluations, issuance of LTO for new hospitals and

issuance of renewal of LTO for Level 3 and Level 4 hospitals back to the BHFS.

II. OBJECTIVE

This Order, through the re-establishment and implementation of the One-Stop Shop Licensure System for Hospitals at the DOH-CO, aims to standardize the conduct of DOH-PTC evaluations and the regulation of Level 3 and Level 4 hospitals nationwide.

III. SCOPE AND COVERAGE

This Order covers the issuance of PTC for all levels of hospitals, the issuance of LTO for all new Hospitals, any changes in the LTO of existing hospitals and renewal of LTO for Level 3 and Level 4 hospitals by the BHFS, DOH-CO.

The CHDs shall continue with their regulatory function of renewing the LTO of Level 1 and Level 2 hospitals.

IV. DEFINITION OF TERMS

For purposes of this Order, the following terms and acronyms shall have the following definition:

1. Applicant – refers to the Hospital that is applying for the issuance of a DOH-Permit to Construct (DOH-PTC) and subsequently a License to Operate (LTO) the health facility.
2. BHFS – acronym for the Bureau of Health Facilities and Services.
3. CHD – acronym for the Center for Health Development.
4. CO – acronym for the Central Office of the DOH.
5. DOH – acronym for the Department of Health.
6. DOH – PTC – refers to the DOH Permit To Construct issued by the DOH through the BHFS to an applicant who will establish and operate a hospital, upon compliance with required documents set forth in this Order prior to the actual construction of the subject facility. It is also required for hospitals with substantial alteration, expansion or renovation, change in classification, or increase in bed capacity. It is a prerequisite for LTO.
7. FDA – acronym for the Food and Drug Administration.
8. HFERC – acronym for Health Facility Establishment Review Committee.
9. LTO – acronym for License to Operate. It is a formal authorization issued by the DOH through the BHFS or the CHD as the case may be, to an individual, partnership, corporation or association to operate a hospital and other health facilities. It is a pre-requisite for accreditation of a hospital and other health facilities by any accrediting body that is recognized by the DOH.
10. One-Stop Shop Licensure – a strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other facilities including but not limited to, the clinical laboratory, HIV testing, drinking water analysis; and blood bank, blood collection unit and blood station; dialysis clinic; ambulatory surgical clinic; pharmacy and medical x-ray facility; excluding drug testing laboratories, medical facilities for overseas workers and seafarers, hospital-based drug abuse and treatment rehabilitation center, facility using radioactive material that are currently regulated by the Philippine Nuclear Research Institute (PNRI) and performance of kidney transplantation.

V. POLICIES

A. One-Stop Shop Licensure for Hospitals

1. General Policies

- a) The DOH-CO through the BHFS shall implement the One-Stop Shop Unit for licensure of new hospitals including renewal of LTO of Level 3 and Level 4 hospitals. The Secretary of Health or his authorized

representative shall issue the LTO of all new hospitals including renewal of LTO of Level 3 and Level 4 hospitals.

b) The CHDs shall retain issuance of the renewal of LTO for all Level 1 and Level 2 hospitals under its current licensing tasks and management following the One-Stop Shop Licensure System for Hospitals embodied in Administrative Order No. 2007 – 0021 “Harmonization and Streamlining of the Licensure System for Hospitals.”

2. Specific Policies

a) Organizational Structure

1) The One-Stop Shop Secretariat at the DOH-CO shall be composed of personnel from the BHFS and the FDA detailed on a full time basis. The One- Stop Shop Unit that will house the secretariat shall be located at Building 15 DOH San Lazaro Compound Rizal Avenue, Manila. The Director IV of the BHFS shall oversee the day-to-day operations of the Secretariat.

2) The One-Stop Shop Secretariat at the DOH-CO shall be trained by the BHFS and the FDA to evaluate the completeness of the application, answer queries of applicants and perform other related functions.

3) The BHFS and the FDA shall provide office supplies and equipment to the One-Stop Shop Secretariat at the DOH-CO.

4) The One-Stop Shop Secretariat at the CHD level shall be supervised by the Chief of the regulation division.

b) DOH-PTC

1) The DOH-CO through the BHFS shall create a Health Facility Establishment Review Committee (HFERC) to review all applications for DOH-PTC with respect to compliance with the guidelines in the planning and design of hospitals.

i. The HFERC shall be composed of the following personnel:

– Chairman – Director IV of BHFS or his representative.

– Members include, but are not limited to, the following – Physician, nurse, medical technologist, architect/engineer, health physicist, food and drug regulatory officer. Other technical experts may be invited to assist in the evaluation of the DOH-PTC application as the need arises.

ii. The HFERC shall act on applications within five (5) working days after having received the following documents:

– Application for DOH-PTC

– Three (3) sets of site development plans and floor plans signed and sealed by an architect and/or engineer

– Proof of ownership such as DTI/ SEC registration

2) All DOH-PTC applications for hospitals shall be submitted to the DOH-CO.

c) Licensing Process for the Issuance of New LTO

1) The licensing process for the issuance of new LTO at the DOH-CO shall follow the provisions stipulated in Section V. A. 2. d. i. – iii Specific Guidelines on the Issuance of a Single LTO under AO No. 2007 – 0021 and its related issuances and whenever applicable, excluding drug testing laboratories.

2) The One-Stop Shop secretariat at the DOH-CO shall process the LTO of all new hospitals for signature of the Secretary of Health or his authorized representative.

3) The One-Stop Shop secretariat at the DOH-CO shall endorse to the BHFS – Records Unit the LTO and other pertinent documents for release.

d) Validity of LTO

The LTO shall be valid for one (1) year from January 1 to December 31.

e) Licensing Process for Renewal of LTO

- 1) The DOH-CO shall renew the LTO of Level 3 and Level 4 hospitals in accordance with the provisions of AO No. 2007 – 0021 and whenever applicable, excluding drug testing laboratories.
- 2) The CHD shall renew the LTO of Level 1 and Level 2 hospitals in accordance with the provisions of AO No. 2007 – 0021 and whenever applicable, excluding drug testing laboratories.
- 3) An expired LTO shall be considered lapsed if not renewed within ninety (90) calendar days from the date of expiration of the LTO. Registration of the hospital shall be automatically cancelled. The management of the hospital shall be required to re-apply for a DOH-PTC, whenever applicable, for registration and for issuance of initial LTO before it can be allowed to operate.

f) Monitoring

The BHFS, the FDA and the CHDs shall intensify monitoring activities through unannounced monitoring visits, the frequency of which shall be determined by the concerned Office.

g) Records and Reports

During the period of recentralization of DOH-PTC evaluations and regulation of Level 3 and Level 4 hospitals, the CHD shall provide the BHFS a copy of status report on violations of the aforementioned hospitals and also a copy of annual hospital statistical reports in their areas of jurisdiction since its decentralization last January 1, 2008.

h) Fees

- 1) The applicant, upon filing an application, shall pay to the DOH-CO/ CHD cashier in charge of the One-Stop Shop Licensure in person or through postal money order, the corresponding fee currently prescribed by the DOH for the One-Stop Shop Licensure System for hospitals.
- 2) All fees for issuance of initial LTO and for renewal of LTO of Level 3 and Level 4 hospitals shall be paid at the DOH-CO cashier.
- 3) All fees for renewal of LTO of Level 1 and Level 2 hospitals shall be paid at the CHD cashier.
- 4) Schedule of fees shall follow Section V. A. Schedule of Fees tables 1 – 4 of Administrative Order No. 2007 – 0023 “Schedule of Fees for the One-Stop Shop Licensure System for Hospitals” and Administrative Order No. 2007 – 0001 “Revised Schedule of Fees for Certain Services Rendered by the BHFS and CHD in Relation to the Regulation of Health Facilities and Services and Validity Period of LTO, Accreditation, Authority to Operate, and Clearance to Operate for Certain Health Facilities and Services” and other related and/ or future issuances by the DOH through the BHFS.

i) Investigation and Hearing of Charges or Complaints

Investigation of charges or complaints involving Level 3 and Level 4 hospitals shall be lodged with the regulatory Bureau concerned. The regulatory Bureau concerned shall conduct an investigation and make a decision.

j) Appeal

Any hospital that has been denied an LTO or whose LTO has been suspended or revoked, after having filed a Motion for Reconsideration with the Bureau concerned, may elevate the case to the Office of the Secretary on appeal within ten (10) days of the decision or denial of the motion for reconsideration. The Bureau concerned shall accordingly elevate the relevant records to the Office of the Secretary for decision. The decision of the Office of the Secretary shall be final and executory.

B. Violations Under the One-Stop Shop Licensure System for Hospitals

1. Guidelines on violations and administrative fines shall follow Section IV. A. Violations and Section IV. B. Sanctions 3. embodied in Administrative Order No. 2007 – 0022 “Violations Under the One-Stop Shop Licensure System for Hospitals.”
2. The suspension or revocation of LTO/ Cease and Desist Order for Level 3 and Level 4 hospitals shall be issued by the Secretary of Health or his duly authorized representative and enforced by the BHFS.

VI. TRANSITORY PROVISIONS

1. The CHDs, upon effectivity of this Order, shall submit to the BHFS an inventory report of all pending applications for PTC, initial LTO and renewal of LTO of Level 3 and Level 4 hospitals in their areas of jurisdiction since its decentralization last January 1, 2008.
2. All new requests for hospital PTC, issuance of initial LTO of hospitals and renewal of LTO of Level 3 and Level 4 hospitals shall be directed to the BHFS.
3. The foregoing provisions shall be temporary in nature and fulfillment of the conditions in this Order under Section I. Background (a) to (d) will merit the decentralization again of these functions to the CHDs.

VII. REPEALING CLAUSE

Provisions from previous issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded and modified accordingly.

VIII. SEPARABILITY CLAUSE

In the event that any provision or part of this Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

IX. EFFECTIVITY

This Order shall take effect fifteen (15) days after its approval and publication in a newspaper of general circulation.

Adopted: 14 December 2010

(SGD.) ENRIQUE T. ONA, M.D.
Secretary of Health

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