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REVISED GUIDELINES IN THE IMPLEMENTATION OF THE ONE-STOP SHOP LICENSING SYSTEM

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I. RATIONALE/BACKGROUND

Administrative Order (A.O.) No. 2007-0021, known as, "Harmonization and Streamlining of the Licensure System for Hospitals" was issued on June 6, 2007, to harmonize and streamline the systems and processes that will make health regulation more rational and client responsive. The One-Stop Shop (OSS) Licensing System was adopted, and entailed transaction with one regulatory office in the Department of Health (DOH), a unified inspection team, and issuance of a single license for hospitals which covered their ancillary services and other health facilities/services. The application of the OSS Licensing System expanded to include non-institution based health facilities with ancillary services, such as Medical Facilities for Overseas Workers and Seafarers (MFOWS), Ambulatory Surgical Clinics (ASC), Dialysis Clinics, based on A.O. No. 2008- 0027, known as "One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services."

Recent changes, such as the passage of Republic Act. No. 9711 or the Food and Drug Administration (FDA) Act of 2009, necessitated transfer of the then DOH Bureau of Health Devices and Technology (BHDT) to Alabang, Muntinlupa, when it became the FDA-Center for Device Regulation, Radiation Health and Research (CDRRHR). Consequently, the filing of application and payment of fees for radiation facilities are now received at the FDA main office. Moreover, the varied modes of payment (direct to DOH Central/Regional Cashier, online bank payments), the separate schedules for inspection, and the different processing timelines being followed by the concerned regulatory offices are no longer in consonance with the OSS Licensing System, and contributed further to the delay in the issuance of the DOH-License to Operate (DOH-LTO) or DOH- Certificate of Accreditation (DOH-COA).

Cognizant of the situation and the need for a more efficient and harmonized system in the issuance of DOH-LTO and DOH-COA, the OSS Licensing System is to be adopted once again. As a refinement to the current regulatory scheme and to create more impact by making the licensing process timely, easy and convenient to the clients, the concerned regulatory offices shall accept and process applications online through the Online Licensing and Regulatory System (OLRS). Furthermore, this is in support of the President's directive to streamline all government processes including regulation.

The implementation of the OSS Online Licensing System shall also cover the other health facilities with ancillary services, such as non-hospital-based MFOWS, non-hospital-based ASCs, non-hospital-based Dialysis Clinics, Infirmaries and Birthing Homes.

II. OBJECTIVE

This Order sets the revised guidelines in the implementation of the One-Stop Shop Licensing System using the Online Licensing and Regulatory System (OLRS) for the licensure of hospitals and licensure and accreditation of other health facilities with ancillary services.

III. SCOPE

This Order shall apply to the following DOH offices involved in the enforcement of regulatory standards in all government and private hospitals and other health facilities namely: the Health Facilities and Services Regulatory Bureau (HFSRB), the Regional Office-Regulatory, Licensing and Enforcement Division (RO-RLED) and the Food and Drug Administration (FDA), which involves the Regional Field Office (RFO) and the Center for Device Regulation, Radiation Health and Research (CDRRHR).

IV. DEFINITION OF TERMS AND ACRONYMS

1. Applicant – the natural or juridical person who is applying for a License to Operate or Certificate of Accreditation of a hospital or any other health facility

2. Certificate of Compliance (COC) – a form of authorization/permission granted by the Food and Drug Administration which serves as proof of the facility's compliance to the set technical requirements. It is a prerequisite for the issuance of the Department of Health-License to Operate.

3. CDRR – refers to the Center for Drug Regulation and Research of the FDA

4. CDRRHR – refers to the Center for Device Regulation, Radiation Health and Research of the FDA

5. Certificate of Registration – refers to the certificate issued by CDRRHR to compliant Magnetic Resonance Imaging (MRI) facilities

6. DOH – refers to the Department of Health

7. Department of Health-Certificate of Accreditation (DOH-COA) – refers to the formal authorization issued by DOH to an individual, partnership, corporation or association to operate a health facility. It refers to compliance to standards set for a particular purpose such as, but not limited to, HIV testing, drug testing, water analysis, issuance of medical fitness certification to overseas work applicants, and performance of kidney transplant. These standards cover input/structural, process and outcome/output standards.

8. Department of Health-License to Operate (DOH-LTO) – a formal authority issued by DOH to an individual, agency, partnership or corporation to operate a hospital or other health facility. It is a prerequisite for accreditation of a health facility (regulated by HFSRB) by any DOH-recognized accrediting body for Quality Management System, such as International Organization for Standardization (ISO).

9. FDA – refers to the Food and Drug Administration

10. Health Facility – refers to institution, whether stationary or mobile, land based or otherwise, that provides healthcare and other health-related establishment which provides diagnostics, therapeutic, rehabilitative, palliative and/or related health care services except medical radiation facilities and hospital pharmacies.

11. Health Facility Evaluation and Review Committee (HFERC) – refers to the committee that reviews all applications for Department of Health-Permit to Construct (DOH-PTC) with respect to compliance with the guidelines in planning and design of health facilities.

12. Health Facilities and Services Regulatory Bureau (HFSRB) – the Bureau of DOH in charge with the implementation of these rules and regulations.

13. Hospital – a place devoted primarily to the maintenance and operation of health facilities for the diagnosis, treatment and care of individuals suffering from illness, disease, injury or deformity or in need of obstetrical or other surgical, medical and nursing care. It shall also be construed as any institution, building or place where there are installed beds, cribs or bassinets for twenty-four hour use or longer by patients in the treatment of diseases.

14. Initial Applications – refer to applications by newly constructed health facilities, changes in the circumstances of the facility, such as, but not limited to, change of ownership, transfer of site, and increase in bed and major alterations or renovations.

15. One-Stop Shop (OSS) Licensing System – a strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other health facilities including, but not limited to, the clinical laboratory, HIV testing, drinking water analysis and drug testing; blood bank, blood collection unit and blood station; dialysis clinic; ambulatory surgical clinic; pharmacy; and medical x-ray facility; but excluding hospital-based Medical Facilities for Overseas Workers and Seafarers (MFOWS), hospital-based Drug Abuse Treatment and Rehabilitation Center, hospital-based Stem Cell Facility, facilities for kidney transplantation, and facility using radioactive material that are currently regulated by the Philippine Nuclear Research Institute (PNRI). The OSS shall also apply to non-hospital-based Medical Facilities for Overseas Workers and Seafarers, non-hospital-based Ambulatory Surgical Clinics, non-hospital-based Dialysis Clinics, Infirmaries and Birthing Homes.

16. Recommendation Letter (RL) – a form of authorization/permission granted by the RFO and CDRRHR of the Food and Drug Administration to facilities with waived inspection but have proven compliance to documentary

requirements. These facilities shall be subject to Post Licensing Inspection (PLI) prior to the issuance of the Certificate of Compliance.

17. 1 RFO – refers to the Regional Field Office of the FDA.

18. RO-RLED – Regional Office-Regulation Licensing and Enforcement Division

V. IMPLEMENTING MECHANISMS

A. General Guidelines

1. All hospitals and other health facilities must secure a DOH-LTO or DOH- COA, whichever is applicable, and must be compliant at all times with the licensing standards and requirements set forth by HFSRB and FDA.

2. The Certificate of Need (CON), when applicable, issued by the Regional Office and the Department of Health-Permit to Construct (DOH-PTC), issued by the HFSRB or the RO-RLED, are prerequisites for the issuance of the DOH-LTO or DOH-COA.

3. The guidelines for the OSS implementation shall be strictly followed at the central and the regional levels of the involved DOH regulatory offices.

4. The HFSRB shall be responsible for the initial and renewal of DOH-LTO of levels 2 and 3 general hospitals and specialty hospitals, non-hospital- based MFOWS, non-hospital-based ASCs and non-hospital-based dialysis clinics.

5. The RO-RLED shall be responsible for the initial and renewal of DOH-LTO of birthing homes, infirmaries, and level 1 hospitals and their add-on facilities, for example, dialysis clinic in a level 1 hospital.

6. All applications, whether for initial or renewal, for DOH-LTO or DOH-COA shall be processed through the Online Licensing and Regulatory System (OLRS), once the system is fully functional.

7. The HFSRBRO-RLED and FDA (RFO and CDRRHR) shall assign OSS evaluators for the assessment of all submitted applications and corresponding documentary requirements.

8. At the Central Office, the Director IV, or in his/her absence or unavailability or when delegated, the Director III of HFSRB, shall approve the issuance of the DOH-LTO or DOH-COA of the health facility.

9. At the Regional Office, the Director IV, or in his/her absence or unavailability or when delegated, the Director III of the RO-RLED, shall approve the issuance of the DOH-LTO or DOH-COA of the health facility.

10. A single DOH-LTO or DOH-COA shall be issued to the health facility, and shall include:

a) Category of the facility;
b) Authorized bed capacity (when applicable);
c) Ancillary services and other regulated health facilities regardless of ownership, beyond the requirement for the category of that particular health facility; and
d) Validity period

11. The OSS Licensing System shall be applicable to all health facilities and ancillary services within the hospital premises, except for the following health facilities, which shall require a separate application for DOH-COA:

a) Medical Facilities for Overseas Workers and Seafarers (MFOWS);
b) Drug Abuse Treatment and Rehabilitation Center (DATRC);
c) Human Stem Cell and Cell-based or Cellular Therapy Facility; and
d) Facilities for Kidney Transplantation

12. Sanctions for violations meted out for ancillary services and other health facilities, regardless of ownership, shall be borne by the hospital or health facility where they are located.

13. A database of all licensed health facilities under the OSS shall be integrated into the OLRS.

B. Specific Guidelines

1. Licensing or Accreditation Process - Initial Application (See Annex A* for the Process Flow of Initial Application)

a) Filing of application for initial DOH-LTO/DOH-COA shall be from the start of the working day of the year to November 15.

b) Initial applicants shall create an account at the OLRS webpage. The user name and password shall be safeguarded by the client, and shall be used to register for all transactions.

c) Once registered, the applicant may log in to access and fill out the application forms. The corresponding fees for the applied health facilities/services shall be shown to guide the client in the computation of fees due to each agency. The applicant shall then encode and/or upload the documentary requirements including scanned copy of the proofs of payment for HFSRB/RO-RLED and FDA.

d) The non-refundable application fee shall be paid to the corresponding regulatory offices: for HFSRB to the DOH cashier, for the RO-RLED to the RO Cashier and for RFO and CDRRHR through FDA cashier or bank payments specified by the FDA. Applicant shall provide proofs of payment, such as scanned copy of the official receipt and deposit slip/on-coll payment slip.