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Department of Health
OFFICE OF THE SECRETARY

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June 6, 2007

ADMINISTRATIVE ORDER

No. 2007 – 0021

SUBJECT: Harmonization and Streamlining of the Licensure System for Hospitals

I. Background / Rationale

Regulatory reform is a component of Department of Health's (DOH) reform initiative known as FOURmula One for Health. One of the supply-side strategies identified in the reform agenda is to harmonize and streamline systems and processes to make health regulation more rational and client-responsive. This end shall be achieved through several mechanisms that include the establishment of a One-Stop Shop for the licensure of hospitals and the decentralization of appropriate regulatory functions to the Centers for Health Development (CHDs).

Under the current regulatory regime, a prerequisite for the grant of a license to operate to a hospital is the acquisition of separate licenses for its ancillary services, such as the clinical laboratory, x-ray facility and pharmacy. Furthermore, if the hospital has other facilities such as blood bank, blood collection unit, or blood station, a separate license or authority to operate must be secured for these facilities. In securing these licenses, the hospital has to transact with different regulatory offices in the DOH. Thus it is not surprising that during dialogues and consultations, stakeholders frequently urge the DOH to streamline regulatory processes. With the establishment of a One-Stop Shop for the licensure of hospitals, a single license would be issued, which shall also cover their ancillary and other facilities. The licensee would eventually be transacting with a single regulatory office in the DOH, thus minimizing costs incurred in relation to the license application process.

The decentralization of the licensing process for hospitals to the CHDs is another strategy to streamline regulatory systems and processes. Decentralization would benefit both the government and the private sector by reducing the cost of regulation as well as the transaction costs incurred by the latter. It would also free-up resources that could be used to strengthen standards development, enforcement, surveillance as well as the oversight functions of the DOH regulatory offices.

II. Objective

This Order sets the guidelines for the harmonization and streamlining of the licensure system for hospitals through the following policy directives:

- 1) Establishment of One-Stop Shop Licensure System for Hospitals; and
- 2) Decentralization of the licensing process to the CHD.

III. Scope and Coverage

This Order shall apply to the DOH regulatory offices, namely the Bureau of Food and Drugs, Bureau of Health Devices and Technology, Bureau of Health Facilities and Services, and Centers for Health Development, which are involved in the enforcement of regulatory standards in all government and private hospitals.

IV. Definition of Terms

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

1. **Automatic Renewal of License** – a licensing process in which the License to Operate shall be processed and issued immediately without inspection of the health facility, upon the submission of required documents.
2. **BFAD** – refers to the Bureau of Food and Drugs
3. **BHDT** – refers to the Bureau of Health Devices and Technology
4. **BHFS** – refers to the Bureau of Health Facilities and Services
5. **Certificate of Compliance** – an internal document to be issued by the respective regulatory offices to attest compliance of the licensee to the bureaus' specific rules and regulations.
6. **CHD** – refers to the Center for Health Development
7. **CO** – refers to the Department of Health Central Office
8. **CON** – refers to the Certificate of Need to establish a new general hospital
9. **DOH** – refers to the Department of Health
10. **HFERC** – refers to the Health Facility Establishment Review Committee
11. **Hospital** – a health facility for the diagnosis, treatment and care of individuals suffering from deformity, disease, illness or injury, or in need of surgical, obstetrical, medical or nursing care. It is an institution where there are installed bassinets or beds for 24-hour use or longer by patients in the management of deformities, diseases, injuries, abnormal physical and mental conditions, and maternity cases.
12. **Licensee** – refers to a hospital that is applying for a License to Operate
13. **LTO** – refers to the License to Operate
14. **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 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 facility for overseas workers and seafarers, hospital-based drug abuse treatment and rehabilitation center, facility using radioactive material that are currently regulated by the PNRI and performance of kidney transplantation.

15.PNRI – refers to the Philippine Nuclear Research Institute

16.PTC – refers to the Permit to Construct

V. Policies and Guidelines

A. One-Stop Shop Licensure for Hospitals

1. General Guidelines

- a. The establishment and implementation of the One-Stop Shop Licensure System for hospitals at CO and at the CHD shall follow the same guidelines, except for those that are only applicable or specific to either.
- b. The CO shall set up and operate a One-Stop Shop Unit for the initial licensure of hospitals and the renewal of LTO of Level 3 hospitals and Level 4 hospitals until the full decentralization of the licensing process of hospitals to the CHDs.
- c. The CHD shall set-up and operate a One-Stop Shop Unit for the renewal of LTO of Level 1 hospitals and Level 2 hospitals.
- d. There shall be one LTO to cover the operation of the hospital as well as the operation of its ancillary and other facilities.
- e. The LTO of hospitals shall be automatically renewed every year.
- f. For hospitals that are non-compliant with licensing standards and requirements and those found violating existing rules and regulations, automatic renewal of LTO shall not apply. The LTO shall be renewed only when the hospital has already complied with both the licensing standards and requirements and any sanctions that have been imposed for violations.
- g. At the CO, the Secretary of Health or his authorized representative shall issue the LTO of the hospital.
- h. At the CHD, the CHD Director shall issue the LTO of the hospital based on the recommendation of the Chief of the Regulation Division.
- i. Ancillary and other facilities shall comply with existing standards and requirements for licensure or accreditation.
- j. Ancillary and other facilities that are located within the premises of the hospital shall be included in the LTO.
- k. Sanctions for violations involving ancillary and other facilities, regardless of the ownership, shall be borne by the hospital.
- l. The Finance Service of the CO shall formulate the guidelines for the utilization of retained income by the CHDs, BHFS, BHDT, and BFAD.

2. Specific Guidelines – One-Stop Shop Licensure

a. Issuance of a Single License to Operate

- i. A single LTO shall be issued to cover the operation of the hospital, as well as its ancillary and other 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 facility for overseas workers and seafarers, hospital-based drug abuse treatment and rehabilitation center, facility using radioactive material that are currently regulated by the PNRI and performance of kidney transplantation.

- ii. The category of the health facility, its authorized bed capacity, and its ancillary and other facilities, shall be indicated on the LTO.
- iii. Any changes in the service capability of a hospital, including those involving ancillary and other facilities, shall be reflected on the LTO.
- iv. For ancillary and other facilities that are not fully owned by the hospital, a Memorandum of Agreement between the latter and the provider of the ancillary or other service shall be required. The service provider may retain its own name, provided that the name of the hospital shall be appended to the name of the former.

b. Organizational structure

- i. CO
 - a) The One-Stop Shop Secretariat shall be created and composed of technical personnel from BHFS, BHDT and BFAD detailed on a full time basis. The One-Stop Shop Unit that will house the Secretariat shall be located at Bldg 15, San Lazaro Compound, Sta. Cruz, Manila. The Director IV of the BHFS shall oversee the day-to-day operation of the Secretariat.
 - b) The One-Stop Shop Secretariat shall be trained by the BHFS, BHDT and BFAD to evaluate the completeness of the application, answer queries of applicants, and perform other related functions.
 - c) The BHFS, BHDT and BFAD shall provide office supplies and equipment to the One-Stop Shop Secretariat.
- ii. CHD
 - a) The One-Stop Shop Secretariat shall be supervised by the Chief of the Regulation Division.
 - b) The Chief of the Regulation Division shall ensure that the One-Stop Shop Secretariat is trained to evaluate the completeness of the application, answer queries of applicants, and perform other related functions.

c. Permit to Construct

- i. The CHD shall create a Health Facility Establishment Review Committee (HFERC) to review all applications for PTC with respect to compliance with the guidelines in planning and design of hospitals. The HERC shall be composed of the following regulatory personnel:
 - a) Chairman – Chief, Regulation Division
 - b) Members – Physician/Nurse, Architect/Engineer
 Other technical experts may be invited to assist in the evaluation of the PTC application as the need arises.
- ii. The HFERC shall act on applications within five (5) working days after having received the following documents: (a) Application for PTC; (b) Three (3) sets of Site Development Plans and Floor Plans signed and sealed by an Architect and/or Engineer; (c) Proof of Ownership such as DTI/SEC Registration, etc.

d. Licensing Process - Initial

- i. The One-Stop Shop Secretariat shall receive and evaluate completeness of documentary requirements for the application for an LTO.
- ii. The initial LTO shall be issued within thirty (30) calendar days after the official receipt of a complete application and compliance with the standards and technical requirements had been demonstrated during inspection. A complete application means that the required documents as listed in the Application Form for Initial License to Operate a Hospital had been submitted.
- iii. At the CO:
 - a) The One-Stop Shop Secretariat shall distribute to BHFS, BHDT and BFAD the documents that they require to review and evaluate the application.
 - b) The One-Stop Shop Secretariat shall organize the inspection team in close coordination with the BHFS, BHDT and BFAD. Two (2) weeks lead-time shall be given to BHFS, BHDT and BFAD to make available representative(s) to the team. Further, each bureau shall create a pool of inspectors whose priority is inspection.
 - c) The BHFS, BHDT and BFAD shall each issue the Certificate of Compliance respectively within ten (10) working days after the return of the inspection team if the hospital has complied with the standards and technical requirements. It shall be forwarded to the One-Stop Shop Secretariat. In the event of non-compliance of the applicant, the concerned bureau(s) shall notify the applicant of deficiencies.
 - d) The Certificate of Compliance shall indicate the category of the health facility, its authorized bed capacity, as well as basic hospital services, ancillary and other facilities.
 - e) The One-Stop Shop Secretariat shall process the LTO for signature of the Secretary of Health or his authorized representative.
 - f) The One-Stop Shop Secretariat shall endorse to the BHFS – Records Unit the LTO and other pertinent documents for release.
 - g) The suspension/revocation/cease and desist order shall be issued by the Secretary of Health or his duly authorized representative and enforced by the BHFS. Once the licensing process for hospitals is decentralized to the CHDs, suspension/revocation/cease and desist order shall be issued by the CHD director upon the recommendation of the Chief of the Regulation Division.
- iv. At the CHD:
 - a) The CHD shall ensure that the initial LTO is issued to the applicant within the thirty (30) calendar day period after receipt of a complete application.
 - b) For all initial LTO issued without the hospital being inspected, if the health facility is subsequently found to be non-compliant to licensing standards and technical requirements, the CHD Director shall be held accountable.
 - c) Each CHD shall prioritize the initial health facility inspection. The CHD Director shall ensure that the required inspection team is available for inspection work during the appropriate period and dates.

- d) The One-Stop Shop Secretariat shall organize the inspection team. In the regions that have a complete complement of regulatory personnel, a unified inspection team shall be composed of, but not limited to, the following regulatory personnel:
 - 1. Team Leader – Physician
 - 2. Members – Nurse, Architect or Engineer, Health Physicist, Pathologist or Medical Technologist, Pharmacist
- e) CHDs with no complete regulatory personnel complement shall notify the concerned regulatory bureau at least two weeks in advance prior to the schedule of inspection so that the appropriate regulatory personnel from the concerned bureau will be made available for the regional inspection.
- f) The One-Stop Shop Secretariat shall process the LTO for signature of the CHD Director. In the event of non-compliance of the applicant, the One-Stop Shop Secretariat shall notify the applicant of deficiencies. It shall endorse to the CHD Records Unit the LTO and other pertinent documents for release.

e. Validity of the License to Operate

- i. The LTO shall be valid for one year from January 1 to December 31.

f. Licensing Process - Renewal

- i. The DOH CO shall automatically renew the LTO of Level 3 and Level 4 hospitals.
- ii. The CHD shall automatically renew the LTO of Level 1 and Level 2 hospitals.
- iii. During the first year of implementation of the One-Stop Shop Licensure System, the validity of LTO for the hospital and its ancillary and other services shall be synchronized.
- iv. The LTO of all existing hospitals shall be renewed by January 1, 2008.
 - a) All LTOs of hospitals and their ancillary and other facilities issued in 2007 shall expire by December 31, 2007.
 - b) Hospitals whose LTO was issued in 2007, shall be required to renew the LTO beginning October 1, 2007 to December 31, 2007. However, the hospital shall be exempt from payment of the corresponding renewal of LTO fee for the health facility or its ancillary and other facilities and services.
 - c) The BHFS shall send, before October 1, 2007, an Application Form for Renewal of License to Operate a Hospital to all hospitals that were granted an initial LTO in 2007 and to all Level 3 and Level 4 hospitals whose LTOs were renewed in 2007.
 - d) The CHD shall send, before October 1, 2007, an Application Form for Renewal of License to Operate a Hospital to all Level 1 and Level 2 hospitals whose LTOs were renewed in 2007.

- v. Applications for renewal of LTO shall be filed beginning on the first day of October until the last day of November of the current year. A discount on the renewal fee shall be granted if a complete application is filed during this period.
- vi. Automatic renewal of LTO shall be done immediately or not later than five (5) working days after the following documents are received by the One-Stop Shop Secretariat: (a) Notarized Application Form for Renewal of License to Operate a Hospital; (b) Sworn Statement that the hospital is compliant with the standards and technical requirements set forth by the DOH; and (c) proof of payment of corresponding fee.
- vii. When there are changes in the circumstances of the LTO that is being renewed, the application shall be subject to the usual process for the issuance of initial LTO, which means that an inspection shall be conducted prior to issuance of LTO.
- viii. When an LTO is expired and not renewed for a period of less than one (1) year after expiration date:
 - a) The hospital shall be required to pay a surcharge of 100% of the renewal fee, over and above the renewal fee.
 - b) There shall be a gap in the validity of the LTO from the date of expiration until the date of issuance of renewal of LTO.
- ix. When an LTO is expired and not renewed for a period of one (1) year or more after expiration date :
 - a) The LTO shall be considered lapsed and registration of the hospital shall be cancelled.
 - b) The hospital shall be required to re-apply for PTC and for registration and issuance of initial LTO before it can be allowed to operate.
 - c) General hospitals shall secure a CON as a requirement for PTC.

g. Monitoring

- i. All licensed hospitals shall comply with regulatory standards and requirements at all times.
- ii. To ensure compliance to regulatory requirements and to compensate for the automatic renewal of LTO, the CHD and BHFS, BHDT and BFAD shall intensify monitoring activities through unannounced monitoring visits, the frequency of which shall be determined by the concerned office. BHFS, BHDT and BFAD shall furnish the CHD a copy of the monitoring report and recommendations.
- iii. Violations found during monitoring shall be appropriately acted upon by the BHFS, BHDT, BFAD and CHD.

h. Reports

- i. The CHD shall furnish the BHFS a copy of the CON Evaluation Tool and other supporting documents immediately after the CON application has been approved or disapproved.
- ii. The CHD shall provide the BHFS, BHDT and BFAD a copy of the Summary of Evaluation of hospitals inspected for issuance of initial LTO as soon as possible.

- iii. The CHD shall furnish the BHFS the following reports on the indicated date:
 - a) Annual Report of Licensed Hospitals (not later than January 15 of the following year)
 - b) Quarterly Status Report of Initial Applications (not later than the 15th day of the following month)
 - c) Quarterly Report on Suspension/Revocation/Cease and Desist Orders issued (not later than the 15th day of the following month)
 - d) Annual Summary of Hospital Performance (not later than January 31 of the following year)
- iv. The BFAD, BHDT and BHFS shall formulate a standard reporting form.
- v. The BHFS shall maintain a database of all licensed hospitals, indicating the category, service capability in terms of clinical, ancillary and other services being provided, authorized and implementing bed capacity, and other relevant information.

i. Fees

- i. The applicant, upon filing an application, shall pay to the CHD Cashier/DOH 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.
- ii. Beginning October 1, 2007, all renewal fees shall be paid at the CHD Cashier.
- iii. Beginning January 1, 2008, all fees and shall be paid at the CHD Cashier.
- iv. For all ancillary and other facilities covered by the One-Stop Shop Licensure System for hospitals whose LTO/accreditation/ authority to operate validity period was increased to three (3) years by virtue of Administrative Order No. 2007-0001, the renewal fee shall be equivalent to one-third (1/3) of the renewal fee stipulated in the aforementioned Order.

j. Investigation and Hearing of Charges or Complaints

- i. Upon filing of charges or complaints by any individual, corporation, association, or organization, against any hospital, or any of its personnel who has violated or is violating the provisions of laws and/or rules and regulations for the regulation of hospitals and their ancillary and other facilities, the CHD shall investigate and verify whether the hospital concerned, or any of its personnel, is guilty of the charges or complaints.
- ii. If, upon investigation and hearing, the hospital concerned, or any of its personnel is found violating the provisions of existing laws, and/or rules and regulations for the regulation of hospitals and their ancillary and other facilities, the CHD Director shall impose the corresponding sanctions; *provided that*, if any of the personnel of government health facilities are involved, they shall be subject to appropriate disciplinary/administrative action in accordance with Civil Service rules; *provided further that*, if any of the involved personnel of hospitals are professionals subject to the Professional Regulation Commission, then the report finding

that said personnel are guilty shall be considered as a formal complaint against them and shall be immediately filed with their respective Professional Regulatory Boards. These actions, of course, are without prejudice to taking the case to judicial authorities for appropriate action.

- iii. The CHD may ask the assistance from the BHDT, BFAD and/or BHFS in the conduct of an investigation. It shall provide a copy of the investigation report to the regulatory bureau/s concerned.
- iv. During the transition period for the One-Stop Shop Licensure for hospitals, investigation of charges or complaints shall lodge with the regulatory bureau concerned. The regulatory bureau concerned shall provide a copy of the investigation report to the Office of Secretary for decision.

k. Appeal

- i. 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 CHD concerned, may elevate the case to the Office of the Secretary, who shall now refer the same to the appropriate bureau for review and recommendation. These offices may request for further clarifications and documents or even request for Memoranda to be submitted by the party concerned. In any case, the bureau concerned shall accordingly submit its findings and recommendations to the Office of the Secretary for decision.
- ii. The decision of the Office of the Secretary shall be final and executory.

B. Decentralization of the Regulatory Functions to the CHD

1. Guidelines

- a. The licensing process for hospitals, both for initial LTO and renewal of LTO of Level 3 and Level 4 hospitals, including the issuance of the PTC, shall be decentralized to the CHDs.
- b. All CHDs shall assume the decentralized functions by January 1, 2008. However, CHDs may opt to assume the decentralized functions even before this date.
- c. The CHD shall continue to issue a Certificate of Need (CON) for new general hospitals prior to its grant of a Permit to Construct (PTC).
- d. The BHFS, BHDT, and BFAD shall exercise oversight, supervisory and monitoring functions over the CHDs with regards to the regulation of hospitals, their ancillary and other facilities.
- e. For regions without the complete personnel complement, the CHD may request for personnel from the concerned bureau or nearest CHD to assist in the inspection of the health facility.
- f. The DOH and the CHDs shall ensure that appropriate funds are allocated in the CHD budget to enable the latter to effectively perform the decentralized regulatory functions.
- g. The BHFS, BHDT and BFAD shall provide technical assistance and other forms of support to the CHDs in the latter's capability-building efforts.

2. Transitory Provisions

- a. A transition period shall be observed to give time to the CHDs and the regulatory bureaus to prepare for decentralization. The transition period shall begin on the date of approval of this Administrative Order until September 30, 2007.
- b. The CHDs shall begin to accept applications for renewal of LTO for all hospitals beginning October 1, 2007.
- c. All hospitals that were issued LTOs in 2007 by the BHFS and the CHDs shall be informed by the respective issuing office that applications for renewal of LTO must be submitted to the concerned CHD from October 1, 2007 to December 31, 2007.
- d. The BHFS, BHDT, BFAD and the CHDs shall ensure that all preparatory activities for decentralization commence immediately after the approval of this Administrative Order.
- e. The BHFS, BHDT and BFAD shall train CHD regulatory personnel to handle the decentralized functions.
- f. The BHFS, BHDT and BFAD shall provide the CHD a copy of the historical records of all hospitals and hospital-based facilities in the region.
- g. Upon the approval of this Administrative Order, BHFS, BHDT, BFAD and CHDs shall inform stakeholders about the changes in the licensure system for hospitals under a decentralized and harmonized set-up.

VI. Repealing Clause

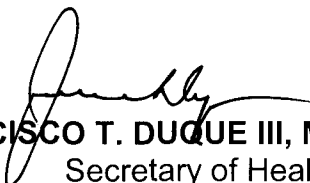
Provisions from previous issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded and modified accordingly.

VII. Separability Clause

In the event that any provision or part of this Order be 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.

VIII. Effectivity

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


FRANCISCO T. DUQUE III, M.D., M.Sc.
Secretary of Health