



June 25, 2008

**ADMINISTRATIVE ORDER**  
**No. 2008 – 0027**

**SUBJECT: 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**

**I. Background / Rationale**

The harmonization and streamlining of systems and processes for health regulation has been identified as one of the supply side strategies in the Department of Health's current reform initiative which is the FOURmula One for Health. Its objective is to make health regulation more rational and client-responsive.

Initial efforts on harmonization and streamlining of regulatory systems and processes involved the establishment of a One-Stop Shop licensure system for hospitals, which featured the issuance of a single license to the hospital that included its ancillary services, a unified inspection process, automatic renewal of license and intensified monitoring and surveillance activities.

It is envisioned that the One-Stop Shop system shall eventually cover other regulated health facilities that provide ancillary services, such as dialysis clinics, ambulatory surgical clinics and medical facilities for overseas workers and seafarers. This system is expected to improve services being provided by the regulatory offices in the DOH as well as reduce transaction costs on the part of license applicants.

**II. Objective**

This Order establishes and sets the guidelines for the 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 that provide ancillary services.

**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 for health facilities.

#### IV. Definition of Terms

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

1. **Ancillary Facilities/ Services** – include but not limited to the following: clinical laboratory, HIV testing, drinking water analysis, pharmacy, and medical and dental x-ray facilities; exclude facilities using radioactive material that are currently regulated by the PNRI.
2. **Applicant** – refers to a health facility that is applying for either a License to Operate or a Certificate of Accreditation.
3. **Automatic Renewal of License or Accreditation**– refers to the immediate processing and issuance of the License to Operate or Certificate of Accreditation without inspection of the health facility, upon the submission of required documents.
4. **BFAD** – refers to the Bureau of Food and Drugs
5. **BHDT** – refers to the Bureau of Health Devices and Technology
6. **BHFS** – refers to the Bureau of Health Facilities and Services
7. **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.
8. **CHD** – refers to the Center for Health Development
9. **CO** – refers to the Department of Health Central Office
10. **COA** – refers to the Certificate of Accreditation issued to a medical facility for overseas workers and seafarers
11. **DOH** – refers to the Department of Health
12. **Health Facility** – refers to a medical facility for overseas workers and seafarers (both hospital-based and non-hospital-based), or a non-hospital-based dialysis clinic or non-hospital-based ambulatory surgical clinic that provides ancillary services
13. **HFERC** – refers to the Health Facility Establishment Review Committee
14. **LGU** – refers to the Local Government Units such as municipalities, cities and provinces.
15. **LTO** – refers to the License to Operate issued to a dialysis clinic or an ambulatory surgical clinic
16. **One-Stop Shop System** – a system of the DOH to harmonize the regulation of medical facilities for overseas workers and seafarers, non-hospital-dialysis clinics, non-hospital-based ambulatory surgical clinics, and their ancillary facilities/ services.

**17. PNRI** – refers to the Philippine Nuclear Research Institute

**18. PTC** – refers to the Permit to Construct, issued to a health facility upon submission of complete documentary requirements and compliance with regulatory standards for physical plant as demonstrated in the evaluation of floor plans.

## **V. Policies and Guidelines**

### **1. General Guidelines**

- a. The CO shall set up and operate a One-Stop Shop Unit for the licensure or accreditation of health facilities covered under this Order.
- b. There shall be one LTO or COA to cover the operation of the health facility as well as its ancillary facilities/ services.
- c. Ancillary facilities/ services that are located within the premises of the health facility shall be included in the LTO or COA.
- d. The health facility and its ancillary facilities/ services shall comply with existing standards and requirements for licensure or accreditation.
- e. The LTO or COA of a health facility shall be automatically renewed except for medical facilities for overseas workers and seafarers.
- f. For health facilities that are non-compliant with licensing or accreditation standards and requirements and those found violating existing rules and regulations, automatic renewal of LTO or COA shall not apply. The LTO or COA shall be renewed only when the health facility has already complied with the licensing or accreditation standards and requirements and any sanctions that have been imposed for violations.
- g. The Director of the BHFS shall issue the LTO or COA of the health facility.
- h. Sanctions for violations involving ancillary facilities/ services, regardless of ownership, shall be borne by the health facility.

### **2. Specific Guidelines**

#### **a. Issuance of a Single License to Operate or Certificate of Accreditation**

- i. A single LTO or COA, whichever applies, shall be issued to cover the operation of the health facility and its ancillary facilities/ services, which include but are not limited to the clinical laboratory, HIV testing, drinking water analysis, pharmacy, and medical and dental x-ray facilities; and exclude facilities using radioactive material that are currently regulated by the PNRI.
  - a) For non-hospital-based dialysis clinic and non-hospital-based ambulatory surgical clinic, ancillary facilities/ services within its premises shall not be issued a separate LTO. The ancillary facilities/ services shall be included in the LTO of the whole health facility.
  - b) For non-hospital-based medical facility for overseas workers and seafarers, all ancillary facilities/ services within its premises shall not be issued a separate COA. The ancillary facilities/services shall be included in the COA of the whole health facility.

- c) For hospital-based medical facility for overseas workers and seafarers, if the ancillary facilities/ services are already part of the hospital license, this shall be indicated in the COA.
- ii. The category of the health facility, and its clinical and ancillary facilities/ services shall be indicated on the LTO or COA.
- iii. Any changes in the service capability of the health facility, including those involving ancillary facilities/ services, shall be reflected on the LTO or COA
- iv. For non-hospital-based dialysis clinics and non-hospital-based ambulatory surgical clinics that have ancillary facilities/ services that are not fully owned by the health facility, a Memorandum of Agreement between the owner of the health facility and the owner of the ancillary facility/ service shall be required. The ancillary facility/ service provider may append its own name to the name of the health facility.
- v. For medical facilities for overseas workers and seafarers, all ancillary facilities/ services must be owned by the health facility.

**b. Organizational Arrangement**

- i. The BHFS shall designate personnel who will act as the One-Stop Shop Secretariat. 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 or his/her duly authorized representative shall oversee the day-to-day operation of the Secretariat.
- ii. The One-Stop Shop Secretariat shall evaluate the completeness of the application, answer queries of applicants, and perform other related functions.

**c. Permit to Construct**

- i. The PTC is a prerequisite for the issuance of the LTO or COA.
- ii. The One-Stop Shop Secretariat shall receive and evaluate completeness of documentary requirements for the application for PTC.
- iii. The HFERC shall act on applications within five (5) working days upon receipt of the following documentary requirements: (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; and (d) proof of payment of PTC fee.

**d. Initial License or Accreditation**

- i. The One-Stop Shop Secretariat shall receive and evaluate completeness of documentary requirements for the application for an LTO or COA, whichever applies.
- ii. For applications for initial LTO or COA, the whole licensing/ accreditation process, commencing from the date of official receipt of a complete application until the issuance or denial of the LTO or COA, shall be completed within thirty (30) calendar days. Otherwise, the initial LTO or COA shall be issued in favor of the applicant. The initial inspection of the health facility to assess compliance with

regulatory standards and requirements shall be conducted within this 30-calendar-day-period.

- iii. A complete application means that the required documents as listed in the Application Form for Initial License to Operate or Certificate of Accreditation have been submitted.
- iv. The One-Stop Shop Secretariat shall distribute to BHFS, BHDT and BFAD the required documents for review and evaluation.
- v. The One-Stop Shop Secretariat, in close coordination with the BHFS, BHDT and BFAD, shall organize the inspection team. 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 of health facilities covered under the One-Stop Shop system.
- vi. 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 health facility 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.
- vii. The Certificate of Compliance shall indicate the authorized services of the health facility.
- viii. The One-Stop Shop Secretariat shall process the LTO or COA for signature of the BHFS Director.
- ix. The One-Stop Shop Secretariat shall endorse to the BHFS–Records Unit the LTO or COA and other pertinent documents for release.

**e. Validity of the License to Operate**

- i. The LTO or COA shall be valid for three years from January 1 of the first year of the validity period to December 31 of the third year of the validity period.

**f. Renewal of License or Accreditation**

- i. The DOH CO shall automatically renew the LTO or COA of the health facility, except medical facilities for overseas workers and seafarers.
- ii. The renewal period for health facilities covered by this Order shall be from October 1 to November 30 of the third and last year of validity of existing LTO or COA.
  - a) During the first year of implementation of the One-Stop Shop System, the validity of LTO or COA for the health facility and its ancillary facilities/ services shall be synchronized.
  - b) The LTO or COA of all existing health facilities shall be renewed by January 1, 2009. All existing health facilities shall apply for a renewal of LTO or COA for the 2009 - 2011 period beginning on October 1, 2008 to December 31, 2008.
  - c) All health facilities with an LTO or COA that is due to expire in 2008 shall have the validity of the LTO or COA automatically extended to December 31, 2008, without paying any additional fee for the extension.
  - d) All health facilities with an LTO or COA that is due to expire between 2009 to 2011 shall be granted pro-rated discounts on the renewal fee, as follows:

- 1) 2009 expiration – discount equivalent to 1/3 of renewal fee.
- 2) 2010 expiration – discount equivalent to 2/3 of renewal fee.
- 3) 2011 expiration – discount equivalent to the full amount of the renewal fee.

Since the renewal fee shall be a composite fee, these discounts shall also be applied to the fees corresponding to the ancillary facilities/ services of the health facility.

- e) An additional 10% discount on the renewal fee shall be granted if the application is filed between October to November 2008.
  - f) The BHFS shall send, before October 1, 2008, an Application Form for Renewal of LTO or COA to all existing health facilities covered by this Order.
- iii. Automatic renewal of LTO or COA 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 LTO or COA; (b) Sworn Statement that the health facility is compliant with the standards and technical requirements set forth by the DOH; and (c) proof of payment of corresponding fee.
  - iv. For the second and third year of LTO or COA validity, the following documents shall be submitted by health facilities with a clinical laboratory, without paying additional fees, beginning on the first day of October until the last day of November of the current year: (a) Notarized Application Form for Renewal of LTO of clinical laboratory; and (b) Sworn Statement that the clinical laboratory is compliant with the standards and technical requirements set forth by the DOH. Otherwise, clinical laboratory services shall be removed from the LTO or COA of the health facility.
  - v. When there are changes in the circumstances of the LTO or COA that warrant a new LTO or COA application based on existing rules and regulations, the health facility shall be subject to the usual process for the issuance of initial LTO or COA, including inspection prior to the issuance of LTO or COA.
  - vi. Sanctions for filing of application for renewal of LTO/ COA after the expiration date shall be in accordance with existing rules and regulations.

#### **g. Fees**

- i. The LTO or COA fee shall be a composite fee, consisting of all the fees that correspond to each clinical and ancillary service being provided by the health facility.
- ii. All fees shall follow the schedule of fees currently prescribed by the DOH.
- iii. The applicant, upon filing an application, shall pay the corresponding fee to the DOH Cashier in-charge of the One-Stop Shop System in person or through postal money order.

#### **h. Monitoring**

- i. The health facility 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 or COA, the BHFS, BHDT, BFAD and CHDs shall intensify monitoring activities through unannounced monitoring visits.
- iii. Monitoring of health facility shall be done at least once a year.
- iv. The BHDT and BFAD and CHDs shall furnish the BHFS a copy of monitoring reports and recommendations.
- v. Violations found during monitoring shall be appropriately acted upon by the concerned office.

**i. Database Management**

- i. The BHFS shall maintain a database of all licensed or accredited health facilities, indicating the category, service capability for both clinical and ancillary services, and other relevant information.

**j. Violations and Sanctions**

- i. Violations relative to existing laws, rules and regulations on the regulation of the health facility and its ancillary facilities/ services, and any other analogous circumstances, shall be subject to the corresponding sanctions, such as imposition of fines, preventive suspension or revocation of LTO or COA, or closure of health facility, as defined by the relevant existing laws, rules and regulations as well as by this Order.
- ii. Non-compliance with licensing or accreditation standards and requirements for equipment shall be considered a violation if deficiencies are not corrected within thirty (30) calendar days after receipt of official notice. Non-compliance with licensing or accreditation standards and requirements for manpower and physical plant shall be considered immediately as a violation.
- iii. With respect to the operation of ancillary facilities/ services, the following shall be considered as a violation:
  - a) Continued operation of an ancillary facility/ service even when it is non-compliant with regulatory standards and technical requirements.
  - b) Continued operation of an ancillary facility/ service despite a cease and desist order with respect to the operation of the facility.
  - c) Continued operation of a regulated facility without a valid license.
- iv. For non-hospital-based dialysis and ambulatory clinics:
  - a) If there are violations relative to existing laws, rules and regulations governing the operation of the health facility:
    - 1) Appropriate sanctions shall be imposed based on existing laws, rules and regulations for the health facility and relevant provisions in this Order.
    - 2) The health facility shall discontinue the provision of all services, including ancillary services, until such time that all violations have been corrected and sanctions have been imposed and complied with.
  - b) If there are violations relative to existing laws, rules and regulations governing the operation of ancillary facilities/ services only:

- 1) The health facility shall discontinue the provision of the ancillary facility/ service.
  - 2) The health facility may be issued an LTO based on compliance with existing rules and regulations, but the ancillary facility/ service shall be removed from the list of authorized services that shall be provided by the health facility.
- v. For medical facilities for overseas workers and seafarers:
    - a) If there are violations relative to existing laws, rules and regulations governing the operation of the health facility and/ or its ancillary facilities/ services:
      - 1) Appropriate sanctions shall be imposed based on existing laws, rules and regulations for the health facility and relevant provisions in this Order.
      - 2) The health facility shall discontinue the provision of all services, including ancillary services, until such time that all violations have been corrected and sanctions have been imposed and complied with.
  - vi. If upon survey or monitoring visits, the health facility is found to be violating existing rules and regulations and as well as other violations stipulated in this Order, the BHFS may immediately preventively suspend the operation of the said health facility. Preventive suspension shall not be more than sixty (60) days.
  - vii. For health facilities whose LTO or COA has been suspended, the LTO or COA shall not be automatically renewed until the suspension order has been lifted.
  - viii. For violations of existing laws, rules and regulations relative to the regulation of ancillary facilities/ services, sanctions shall be borne by the health facility, whether or not the ancillary facility/ service involved is owned by the health facility.
  - ix. Any changes in the service capability of a health facility as a result of sanctions imposed due to violations, including those involving ancillary facilities/ services, shall be reflected on the LTO or COA.
  - x. The order to impose sanctions shall be issued and enforced by BHFS. Assistance from the CHD and LGUs may be sought in the enforcement of sanctions.

**k. Investigation and Hearing of Charges or Complaints**

- i. Upon filing of charges or complaints by any individual, corporation, association, or organization, against any health facility, or any of its personnel who has violated or is violating the provisions of laws and/or rules and regulations for the regulation of the health facilities and their ancillary facilities/ services, the BHFS shall investigate and verify whether the health facility concerned, or any of its personnel, is guilty of the charges or complaints.
- ii. If, upon investigation and hearing, the health facility concerned, or any of its personnel is found violating the provisions of existing laws, and/ or rules and regulations for the regulation of health facilities and their ancillary facilities/ services, the BHFS 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 health facilities 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 BHFS may ask the assistance of the BFAD or BHDT in the conduct of the investigation, if the charge or complaint involves ancillary facilities such as pharmacy or X-ray facility. It shall provide a copy of the investigation report to the regulatory bureau/s concerned.

#### **I. Appeal**

- i. Any health facility that has been denied an LTO or COA, or whose LTO or COA has been suspended or revoked, after having filed a Motion for Reconsideration with the BHFS, 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.

#### **VI. Repealing Clause**

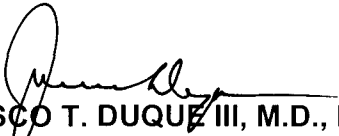
Provisions from previous issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded and modified accordingly.

#### **VII. Separability Clause**

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

#### **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