DEPARTMENT OF HEALTH

HEALTH FACILITIES AND SERVICES REGULATORY BUREAU
OUTLINE

• Moratorium for the Compliance with the Licensing Requirements of Hospitals, Infirmarys, Birthing Homes and Ambulance
  • DC No. 2017-0363 dated October 25, 2017
  • DC No. 2017-0361 dated December 1, 2017

• Revised Guidelines for Licensing Ambulances and Ambulance Service Providers
  • AO 2018-0001 dated January 26, 2018

• Issuances on Blood Service Facilities
  • DC No. 2017-0379 dated December 8, 2017
  • DC No. 2018-0039 dated February 15, 2018

• Updates on Clinical Laboratories
  • DC No. 2018-0049 dated January 16, 2018 (NEQAS)
  • DC No. 2018- dated (Referral, Sending-out, or Outsourcing)

• One-Stop Shop Online Licensing System

• Revised Assessment Tools for Hospitals
### Reiteration of the End of Moratorium for Compliance to the Licensing Requirements on December 31, 2017

| Hospitals | • File renewal application documents  
| Infirmaries | • Corrective measures to violations and deficiencies  
| Birthing Homes |  
| Ambulance Service | Full compliance to licensing standards and requirements  

| Moratorium | Dec. 31, 2017  
| HFSRB AND RLEDs | Full implementation of Regulatory Policies  

| • Provide technical assistance  
| • Consultative meetings  
| • Review and revision of policies  

| • Post-renewal monitoring activities  
| • Reclassify health facilities according to service capability  

Jan. 1, 2018
RECENT DOH ISSUANCES ON APPLICATION OF LICENSE TO OPERATE, CERTIFICATE OF ACCREDITATION, AND PERMIT TO CONSTRUCT
DC NO. 2017-0363: REQUIREMENTS FOR THE RENEWAL OF LICENSE TO OPERATE OF HOSPITALS AND AMBULANCE SERVICE PROVIDERS FOR 2018

REGIONAL OFFICE RLEDS SHALL:

- Receive notarized duly accomplished application forms and application payment for LTO of ambulances of Levels 1, 2, 3 hospitals and specialty hospitals;
- Process the applications for LTO of ambulances and include the ambulance service in the LTO of Level 1 Hospitals for 2018;
- Forward application forms and proof of payment of LTO of ambulances of Levels 2 and 3 hospitals and specialty hospitals to HFSRB for processing;
- Conduct post-licensing inspection of the ambulances; and
- Submit a list of all applications for LTO of ambulances received by RLED to HFSRB for processing of their DOH logo stickers and inclusion of these ambulances in the registry.
HFSRB and RLED of the Regional Offices shall observe the following cut-off dates in receiving applications from all health facilities:

- **Permit to Construct**: November 30, 2017
- **New/Initial (LTO/COA)**: November 30, 2017
- **Renewal (LTO/COA)**: December 15, 2017
LICENSING OF AMBULANCES AND AMBULANCE SERVICE PROVIDERS
A.O. No. 2018-0001
Revised Rules and Regulations Governing the Licensure of Land Ambulances and Ambulance Service Providers

• Issued on January 26, 2018
• Published February 11, 2018 - PDI and Philippine Star
• Effectivity date: February 27, 2018

• Major revisions done are as follows:
  • Categorization of Ambulances
    ➢ Type I- equipped with Basic Life Support (BLS)
    ➢ Type II- equipped with Advance Life Support (ALS)
  • Minimum qualifications of Personnel
  • No prescribed quantity for Equipment, Medicines and Supplies

• Land Ambulance - a vehicle designed and equipped with basic or advance life support for transporting patients to, from, and between places of treatment by land.

• Patient Transport Vehicle (PTV) - any form of land vehicle designed to transport patients whose condition is of a non-life threatening nature.
## Category of Ambulances Required Among Health Facilities

<table>
<thead>
<tr>
<th>Type of Facility</th>
<th>Category of Ambulance Required</th>
<th>If Outsourced with a DOH Licensed Ambulance Service Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty and Level 3 Hospitals</td>
<td>Type II (ALS) Ambulance</td>
<td>• The ambulance servicing the hospitals should be Type II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• There should be a MOA between a hospital and the ASP (whether government or privately owned)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The ambulance vehicle should be stationed at the hospital at all times.</td>
</tr>
<tr>
<td>Level 2 Hospitals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 1 Hospitals</td>
<td>Type I (BLS) Ambulance + MOA with a hospital of higher level. May opt to have a Type II Ambulance</td>
<td>• The ambulance servicing the hospitals may either be Type I or Type II</td>
</tr>
<tr>
<td>Infirmaries</td>
<td></td>
<td>• There should be a MOA between the hospital and the ASP (whether government or privately owned)</td>
</tr>
</tbody>
</table>

*Hospitals and infirmaries may opt to have their own Patient Transport Vehicles (PTV) in addition to their ambulances.*
## Personnel Qualifications

<table>
<thead>
<tr>
<th>Category of Ambulance</th>
<th>Minimum Qualifications</th>
<th>Training Requirements</th>
</tr>
</thead>
</table>
| **Type I**            | Graduate of any health related 4 year course | CY 2018-2019:  
  - Standard First Aid (SFA)  
  - Basic Life Support (BLS)  

Starting CY 2020 onwards:  
  - SFA + BLS + Emergency Medical Technician (EMT) Training- Basic |
| **Type II**           | Licensed or Registered Nurse (RN) | CY 2018:  
  - Standard First Aid (SFA)  
  - Basic Life Support (BLS)  
  - Advance Cardiac Life Support (ACLS)  

Starting CY 2020 onwards:  
  SFA + BLS + ACLS + EMT Training-Advance / Paramedic Training |
<table>
<thead>
<tr>
<th>Requirements</th>
<th>Type I (BLS)</th>
<th>Type II (ALS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilation and Airway Equipment</td>
<td>✓ (except ET tubes and laryngoscope set)</td>
<td>✓</td>
</tr>
<tr>
<td>Monitoring and/or Defibrillation</td>
<td>✓ (AED)</td>
<td>✓ (Manual)</td>
</tr>
<tr>
<td>Immobilization Devices</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Dressings and Bandages</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>OB Set</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Infection Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication Equipment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient Transport Equipment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Injury Prevention Equipment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>IV Therapy Supplies</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>IV Fluid</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Medicines</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Controlled Medicines</td>
<td>✗</td>
<td>✓</td>
</tr>
</tbody>
</table>
DC No. 2018-0143: Registration of Patient Transport Vehicles

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 11, 2018

DEPARTMENT CIRCULAR
No. 2018 - 0143

TO: ALL HEADS OF HOSPITALS AND OTHER HEALTH FACILITIES, REGIONAL DIRECTORS, CHIEFS OF THE REGULATORY LICENSING AND ENFORCEMENT DIVISION (RLED), OTHER STAKEHOLDERS CONCERNED

SUBJECT: Registration of Patient Transport Vehicles
Section V.16 of Administrative Order (A.O.) No. 2018-0001 titled Revised Rules and Regulations Governing the Licensure of Land Ambulances and Ambulance Service Providers dated January 26, 2018 stipulates that Patient Transport Vehicles (PTVs) shall not be licensed by the Health Facilities and Services Regulatory Bureau (HFSRB) of the Department of Health but shall be registered with the Bureau using a prescribed form. Registration is required for the building of the registry of PTVs in the country.

In line with the abovementioned provision, the HFSRB has developed the form for the registration of PTVs attached herein as Annex A (also downloadable at hfrsbdoh.gov.ph). The form shall be accomplished by all concerned stakeholders who currently or plan to use patient transport vehicles for their facilities or institutions with reference to the following procedural guidelines in the registration of PTVs:

1. Completely filled-up and notarized forms shall be submitted to HFSRB through the designated regional offices.
1. Completely filled up and notarized forms shall be submitted to HFSRB through the following channels:
   a. walk-in submission at HFSRB
   b. via mail or courier
   c. via e-mail at hfsrb@doh.gov.ph
   d. through the DOH Regional Office- Regulatory Licensing and Enforcement Division who shall then transmit the registration form to HFSRB accordingly

2. Facilities or institutions shall register all their operational PTVs.

3. Registration of a vehicle as a PTV shall only be done once. In cases when a vehicle shall no longer be used as a PTV, the concerned facility or institution should inform HFSRB/RO-RLED through a letter indicating the plate or conduction sticker number of the said vehicle for delisting. The delisted vehicle should then no longer bear the marking “PATIENT TRANSPORT VEHICLE.”
4. The DOH shall not issue any form of certification as proof of registration thus all registrants are advised to keep a copy of their submitted form with HFSRB’s or RORLED’s stamp indicating the date of receipt. For submissions via mail or courier, a letter acknowledging receipt shall be sent to the registrants. Likewise, registrants who submitted via email shall receive an acknowledgement email.

For your information and reference.

By Authority of the Secretary of Health:

ROLANDO ENRIQUE D. DOMINGO, M.D., DPBO
Undersecretary of Health
Health Regulations Cluster
ANEX A

REGISTRATION OF PATIENT TRANSPORT VEHICLE (PTV)

Owner of Vehicle: ____________________________

(as reflected in the Land Transportation Office (LTO) Registration)

Complete Address: ____________________________

No. & Street ____________________________ Barangay ____________________________

City/ Municipality ____________________________ Province ____________________________ Region ____________________________

Tel./Fax. No.: ____________________________ Mobile No.: ____________________________

E-Mail Address: ____________________________

I. Classification:

A. According to institutional Character:

Institution-Based:

PTVs owned by Health Facilities regulated by the Department of Health (DOH), tick (+) appropriate box:

☐ Hospital

☐ General: ☐ Level 1 ☐ Level 2 ☐ Level 3

☐ Specialty, please specify ____________________________

☐ Infirmary

☐ Birthing Home

☐ Others, please specify ____________________________

Non-Institution-Based/ Free-Standing:

PTVs not owned by Health Facilities regulated by the DOH, tick (+) appropriate box:

☐ Provincial Health Office

☐ Rural Health Unit

☐ Municipal Health Office

☐ Barangay Health Station

☐ City Health Office

☐ Health Center

☐ Others, please specify ____________________________

B. According to Ownership:

☐ Government

☐ Private

II. No. of Vehicles for Registration:

List down the LTO Certificate of Registration and Plate Number or Conduction Sticker Number per vehicle applied for registration:

<table>
<thead>
<tr>
<th>Vehicle</th>
<th>LTO Certificate of Registration</th>
<th>Plate Number or Conduction Sticker Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Acknowledgement

REPUBLIC OF THE PHILIPPINES
CITY/ MUNICIPALITY OF _________) S.S.

I, ____________________________, of legal age, ________ a resident

Name ____________________________ Civil Status ____________________________ Age ________

of ____________________________, after having been sworn in accordance with

Address ____________________________

law hereby depose and say that I am executing this affidavit to attest to the

completeness and truth of the foregoing information for the Registration of Patient

Transport Vehicles in the Philippines pursuant to Administrative Order No. 2018-0001

"Revised Rules and Regulations Governing the Licensure of Land Ambulances and

Ambulance Service Providers."


__________________________

Signature

Before me, this _____ day of _______ 20___ in the City/Municipality of

__________________________, Philippines, personally appeared the above affiant with

Community Tax Certificate No. ____________________________ issued on ____________

at ____________, known to me to be the same person/s who executed the

foregoing instrument and they acknowledge to me that the same is their free act and

deed.

IN WITNESS WHEREOF, I have hereunto set my hands this _____ day of

__________________________, 20___


_____________ NOTARY PUBLIC

Doe. No. ________________

Page No. ________________

Book No. ________________

Series of ________________

Notary Public

My Commission

Expires

Dec. 31. ________

Page 1 of 2

Form: PTVA-1

Revision 00

04/18/2018

Page 1 of 2
LICENSING OF CLINICAL LABORATORIES AND BLOOD SERVICE FACILITIES
Department Circular No. 2017-0379: One (1) Year Suspension for the Compliance to the Requirements for the Certificate of Inclusion

• Department Memorandum 2016-0448 has set the issuance of a Certificate of Inclusion (COI) in the Regional Blood Service Network as a pre-licensing requirement for all Blood Service Facilities (BSF).

• There are some BSFs which are still in the process of completing the requirements for the COI.

• HFSRB suspends the requirement of COI for the renewal of 2018 License to Operate of hospitals.
Department Circular No. 2018-0039: Revised Assessment Tool for Licensing Blood Service Facilities dated February 15, 2018

- DOH A.O. No. 2008-0008 dated May 2, 2008 has set the rules and regulations governing the licensure of Blood Service Facilities (BSFs).

- As part of the procedural guidelines, BSFs shall strictly follow the minimum standard reqs. prescribed in the Assessment Tool.

- A revision of the Assessment Tool has been made to be more consistent with the implementation guidelines.

- Effectivity: February 26, 2018
What are the Major Changes?
Headship

1.2.1 The BSF is headed by a duly licensed physician who is:
For Hospital-based Blood Stations
1.2.1.1 Certified in Clinical Pathology by the Philippine Board of Pathology of the PSP,
   1.2.1.1.1 Specialty Board Certificate
   1.2.1.1.2 Resume
   1.2.1.1.3 Notarized Contract of Employment
   1.2.1.1.4 Job Description

For Blood Center, Hospital Blood Bank and Hospital Blood Bank with Additional Functions
1.2.5.1 Certified in Clinical Pathology by Philippine Board of Pathology of the PSP, and with experience in a blood service facility
   1.2.5.1.1 Specialty Board Certificate
   1.2.5.1.2 Resume
   1.2.5.1.3 Notarized Contract of Employment
   1.2.5.1.4 Job Description
Space Requirements

**Areas for Blood Station – Designated area in the Clinical Laboratory**
- Storage blood bank refrigerator
- Blood typing and Cross matching
- Releasing of blood products

**Areas for BCU and BS/BCU**
- Reception / waiting area – 1.0 m²/person
- Donor Counseling – 5.02 m²
- Physical Exam area for donor – 5.02 m²
- Donor extraction – 6 m² per bed or couch
- Provision of sink for hand washing
- Area for Refrigerator and supplies (at least 1.2 m² per storage unit)
- Preparation Area – 5.02 m²
- Releasing of blood products
- Administrative Office

**Areas for Hospital Blood Bank Area of at least 19 m²**
- Areas for blood bank refrigerator, plasma freezer, plasma agitator, and supplies (at least 1.2 m² per storage unit)
- Blood typing and Cross matching Work Counter
- Releasing of blood products

NOTE: Location of HBB must be adjacent or easily accessible to the main clinical laboratory.

**Areas for Hospital Blood Bank with Additional Function**
- **Reception / waiting area – 1.0 m²/person**
- Donor Counseling – 5.02 m²
- Physical Exam area for donor – 5.02 m²
- Donor extraction – 6 m² per bed or couch
- Provision of sink for hand washing
- **Blood screening for TTIs – 10 m²**
- Blood typing and Cross matching Work Counter
- Processing of blood into blood components 4.65 m² per equipment
- Storage facility – 4.65 m² per storage unit
- Releasing of blood products
- Administrative Office

**Reception/Waiting area for HBB++ can be located outside or can be a common area for clinical laboratory.**

**May be carried out within the clinical laboratory if the HBB++ is adjacent to the main clinical laboratory.**

**Areas for Blood Center**
- Reception / waiting area – 1.0 m²/person
- Donor Counseling – 5.02 m²
- Physical Exam area for donor – 5.02 m²
- Donor extraction – 6 m² per bed or couch
- Blood screening for TTIs – 10 m²
- Processing of blood into blood components – 4.65 m² per equipment
- Storage facility – 4.65 m² per storage unit
- Releasing of blood products
- Administrative Office
## Annex A. Number of Personnel

<table>
<thead>
<tr>
<th>BSF Category</th>
<th>Donor Recruitment/ Counselling</th>
<th>Pre-collection / Collection</th>
<th>Testing for TTIs</th>
<th>Component Processing</th>
<th>Compatibility Testing</th>
<th>Releasing</th>
<th>Transfusion Reaction Investigation</th>
<th>Inventory Management</th>
<th>Networking</th>
<th>Total Number of personnel / 24 hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital based Blood Station</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 designated RMT/shift</td>
<td>Same personnel in Releasing</td>
<td>3 designated RMTs</td>
<td></td>
</tr>
<tr>
<td>Non-hospital based Blood Station (Not operating for more than 8 hours)</td>
<td>1 RN or RMT or under board MT trained by DOH recognized training provider</td>
<td>1 RMT</td>
<td>2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT</td>
<td>1 MD per activity</td>
<td>1 RMT plus 1 reliever</td>
<td></td>
<td>Same personnel in Releasing</td>
<td>2 RMTs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-hospital base Blood Station / Blood Collection Unit (BS/BCU)</td>
<td>1 RN or RMT or under board MT trained by DOH recognized training provider</td>
<td>1 RMT</td>
<td>2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT</td>
<td>1 MD per activity</td>
<td>1 RMT plus 1 reliever</td>
<td></td>
<td>Same personnel in Releasing</td>
<td>1 MD 3 RMTs 2 Phlebotomists 1 RN/RMT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Collection Unit</td>
<td>1 RN or RMT or under board MT trained by DOH recognized training provider</td>
<td>1 RMT</td>
<td>2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT</td>
<td>1 MD per activity</td>
<td>1 RMT/shift plus 1 reliever 1 MD (on-call)</td>
<td></td>
<td>Same personnel in Donor Recruitment</td>
<td>1 MD 1 RTM 2 Phlebotomists 1 RN/RMT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Bank</td>
<td>1 RN/RMT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 RMT/shift plus 1 reliever 1 MD (on-call)</td>
<td></td>
<td>4 RMTs 1 RN/RMT</td>
<td></td>
</tr>
<tr>
<td>Blood Bank with additional functions</td>
<td>1 RN</td>
<td>1 RMT</td>
<td>2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT</td>
<td>1 MD per activity</td>
<td>1 RMT/shift plus 1 reliever 1 MD (on-call)</td>
<td></td>
<td>Same RMT assigned in Releasing</td>
<td>Same RN assigned in donor recruitment</td>
<td>1 MD 9 RMTs 2 Phlebotomists 1 RN</td>
<td></td>
</tr>
<tr>
<td>Blood Center</td>
<td>1 RN</td>
<td>1 RMT</td>
<td>2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT</td>
<td>1 MD per activity</td>
<td>1 RMT/shift plus 1 reliever 1 MD (on-call)</td>
<td></td>
<td>Same RMT assigned in Releasing</td>
<td>Same RN assigned in donor recruitment</td>
<td>1 MD 9 RMTs 2 Phlebotomists 1 RN</td>
<td></td>
</tr>
</tbody>
</table>
Non-Participation of a Clinical Laboratory in the External Quality Assessment Program (EQAP) of the National Reference Laboratories

- DOH D.M. No. 2009-0086 dated Sept. 8, 2014, requires the participation of clinical laboratories in the EQAP of the NRLs, and submission of the Certificate of Performance or Certificate of Proficiency (COP) as a requirement for the renewal of LTO.

- Requirements for 2018 renewal of LTO (as per D.M. No. 2017-0185):
  1. 2015 COP and/or Official Receipt of EQAP application; and
  2. Proof of filing of EQAP for 2017

- The DOH in coordination with the NRLs, harmonized the application period and releasing of the certificates.
  - Application period: January to May;
  - Release of COP:
    - RITM and EAMC: November of the same year
    - SACCL, NKTI, and LCP: November of the succeeding
Non-Participation of a Clinical Laboratory in the External Quality Assessment Program (EQAP) of the National Reference Laboratories

- All clinical laboratories shall be required to present their latest Certificates of Performance or Proficiency from each NRLs applicable to their category starting 2019.
- LTO of clinical laboratories which failed to participate in the EQAP shall be renewed, provided that:
  a.) Penalty shall be imposed; and
  b.) Official Receipt (OR) for 2018 EQAP application shall be submitted on or before June 1, 2018.
- For those “new” clinical laboratories, whether newly constructed, recently transferred, or with change in ownership, LTO shall be issued out but:
  a.) A copy of 2018 OR from the NRL shall be submitted to HFSRB or RO-RLEDs on or before June 1, 2018; and
  b.) A copy of 2018 COP shall be submitted for 2019 renewal of LTD except for Certificates of Performance or Proficiency from NRL-SACCL and NRL-LCP.
<table>
<thead>
<tr>
<th>Classification of Clinical Laboratories</th>
<th>Administrative Order</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Free-standing</strong></td>
<td>Section XI of A.O. No. 2007-0027: Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines.</td>
<td>Fine of Php 5,000.00 and Stern warning</td>
</tr>
<tr>
<td><strong>Institution Based:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| a. Hospitals                           | Section IV. b. of A.O. No. 2007-0022: Violation under the One-Stop Shop Licensure System for Hospitals | 1<sup>st</sup> offense: Fine of Php 5,000.00 and/or Stern warning  
2<sup>nd</sup> offense: Fine of Php 30,000.00  
3<sup>rd</sup> offense: Fine of Php 50,000.00  
4<sup>th</sup> offense: Revocation of LTO |
| b. Medical Facilities for Overseas Workers and Seafarers | Section XIII.A. of A.O. No. 2013-0006: Guidelines to “Rules J0: Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipino Act of 1995, as Amended by Republic Act No. 10022 ” | 1<sup>st</sup> offense: Fine of Php 50,000.00 and Stern warning  
2<sup>nd</sup> offense: Fine of Php 100,000.00 and suspension of COA  
3<sup>rd</sup> offense: Revocation of COA |
| c. Non-Hospital-Based Ambulatory Surgical Clinics and Non-Hospital-Based Dialysis Clinics | Section V.j.i of A.O. No. 2008-0027: One-Stop Shop System for the Regulation of Medical Facilities Over Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services | 1<sup>st</sup> offense: Fine of Php 5,000.00 and Stern warning  
2<sup>nd</sup> offense: Preventive Suspension  
3<sup>rd</sup> offense: Revocation of LTO |
Clarification on the Guidelines on Referral or Outsourcing of Clinical Laboratory Services

- Referral, send-out or outsourcing of examinations to other clinical laboratories are *only permitted in the following circumstances*:
  
  1. If the laboratory test to be sent out is *not part of the service capability expected* for the particular category of the referring laboratory; and

  2. If referral of laboratory test is part of the *contingency plan in case of equipment breakdown, this must be properly documented*. Accordingly, the receiving DOH-licensed clinical laboratory shall assure the quality of service through a *notarized Memorandum of Agreements (MOA)*.
Moreover, regardless of ownership, whether owned by the hospital or by another entity, the clinical laboratory, as one of the required ancillary services for the issuance of License to Operate (LTO), should be within the hospital premises and its services shall be available 24/7. There should be a notarized MOA between the hospital and the clinical laboratory, if outsourced.

Likewise, a clinical laboratory found to be sending out tests within their expected service capability, shall be meted out with appropriate sanctions.

For Strict Implementation
RA 10932: AO No. 2018-0012
Implementing Rules and Regulations of Anti-hospital Deposit Law
RA 10932: Anti-Hospital Deposit Law

Enacted - May 24, 2017
Signed by the President - August 3, 2017

SUBJECT: Implementing Rules and Regulation of Republic Act 10932 “An Act Strengthening the Anti-Hospital Deposit Law by Increasing the Penalties for the Refusal of Hospitals and Medical Clinics to Administer Appropriate Initial Medical Treatment and Support in Emergency or Serious Cases, Amending for the Purpose Batas Pambansa Bilang 702, Otherwise Known as “An Act Prohibiting the Demand of Deposits or Advance Payments for the Confinement or Treatment of Patients in Hospitals and Medical Clinics in Certain Cases” As Amended By Republic Act No. 8344, And For Other Purposes”

Section 9 of R.A. 10932, the Department of Health (DOH), in coordination with PhilHealth and the Bureau of Internal Revenue (BIR), and in consultation with Non-Government Offices (NGOs) advocating for patients’ rights and public health, is mandated to promulgate the necessary rules and regulations to carry out the provisions of the aforementioned law.
7 TWG meetings: Aug. 25, 2017 to November 16, 2017

What are the new provisions?

1. Section 3 - After the hospital or medical clinic mentioned above shall have administered medical treatment and support, it may cause the transfer of the patient to an appropriate hospital consistent with the needs of the patient, especially in the case of poor or indigent patients.

Where there is no ambulance available for use by the hospital or medical clinic for the emergency transfer of the patient to a facility where the appropriate care shall be given the local government unit (LGU) where the hospital or medical clinic is located must allow the free use of its emergency vehicle to transport the patient to the hospital or medical clinic where a continuation of care shall be given. The hospital or medical clinic must provide a staff nurse based from the licensing guidelines of DOH on ambulance service provider with advanced cardiovascular life support (ACLS) certification as recognized by DOH or its equivalent to accompany the patient in the emergency vehicle.
3.4. When the patient is no longer under the state of emergency, the hospital should inform the patient that he/she must abide by the internal policies of the hospital.

3.5. The local government unit (LGU) where the hospital or medical clinic is located shall allow the free use of its emergency vehicles to transport the patient if there is no available ambulance in the hospital or medical clinic.

3.5.1. The LGU shall formulate and implement a system wherein it can provide emergency vehicle without delay during emergency and serious cases, if there is no available ambulance in the said hospital or medical clinic.

3.5.2. The LGU shall set up a “hotline” or a “call center” for receiving requests for ambulance 24/7; and

3.5.3. The LGU shall enter into a Memorandum of Agreement or Undertaking with the specific hospital on the free use of its emergency vehicles.
Section 4 - Penal Provisions - any official, medical practitioner or employee of the hospital or medical clinic who violates the provisions of R.A. 10932 shall, upon conviction by final judgment, be punished by imprisonment of not less than six (6) months and one (1) day but not more than two (2) years and four (4) months, or a fine of not less than One hundred thousand pesos (P100,000.00), but not more than Three hundred thousand pesos (P300,000.00) or both, at the discretion of the court. Provided, however, That if such violation was committed pursuant to an established policy of the hospital or clinic or upon instruction of its management, the director or officer of such hospital or clinic responsible for the formulation and implementation of such policy shall, upon conviction by final judgment, suffer imprisonment of four (4) to six (6) years, or a fine of not less than Five hundred thousand pesos (P500,000.00), but not more than One million pesos (P1,000,000.00) or both, at the discretion of the court, without prejudice to damages that may be awarded to the patient-complainant: The established policy referred to in this section shall be in the form of writing such as Circular, Notice, Memorandum, Resolution, Directives, and similar acts. Provided, further, That upon three (3) repeated violations committed pursuant to an established policy of the hospital or clinic or upon the instruction of its management, the health facility’s license to operate shall be revoked by the DOH. The president, chairman, board of directors, or trustees, and other officers of the health facility shall be solidarily liable for damages that may be awarded by the court to the patient-complainant.
Section 5 - A presumption of liability shall arise against the hospital, medical clinic, and the official, medical practitioner, or employee involved in the denial of a patient’s admission to a health facility when the following requisites are present:

5.1. Requisites

5.1.1 The denial of the patient’s admission was pursuant to a policy or practice of demanding deposits or advance payments for confinement or treatment; and

5.1.2 The denial of the patient’s admission was the proximate cause of any of the following:
   5.1.2.1 Death or permanent disability of the patient-complainant;
   5.1.2.2 Serious impairment of the health condition of the patient-complainant; OR
   5.1.2.3 In the case the patient-complainant is a pregnant woman, permanent injury or loss of her unborn child.

5.2. Providing evidence to contest
The presumption can be overcome by the presentation of evidence that one of the requisites is not present.
Section 6 - All complaints for violations of this R.A. 10932 against health facilities shall be filed initially with the Health Facilities Oversight Board under the HFSRB of the DOH.

6.1. The Board shall be appointed by the Secretary of Health and shall be composed of:
   6.1.1. A DOH representative with a minimum rank of Director to serve as Chair;
   6.1.2. A representative from the Philippine Health Insurance Corporation (PhilHealth);
   6.1.3. A representative from the Philippine Medical Association (PMA);
   6.1.4. A representative from private health institutions; and
   6.1.5. Three (3) representatives from non-government organizations (NGOs) advocating for patient’s rights and public health, one of whom would be a licensed physician.

Members can be added as may be deemed necessary by the Board. Further, the DOH Regional Offices shall create their own Oversight Board with the same composition and functions to facilitate the complaints under their jurisdiction.
6.2. Functions of the Board:
   6.2.1. Investigate the claim of the patient through a fact-finding investigation.
   6.2.2. After adjudication, impose administrative sanctions in accordance with R.A. 10932, including the revocation of the health facility’s license.
   6.2.3. Facilitate the filing of the criminal case in the proper courts.
   6.2.4. Develop and implement its own rules and procedures.
   6.2.5. Undertake activities as it may deem necessary to implement these rules and regulation.
Section 7 - Reimbursement of Basic Emergency Care

7.1. PhilHealth shall reimburse the cost of basic emergency care and transportation services incurred by the hospital or medical clinic for the emergency medical services given to poor and indigent patients adopting the resuscitation (emergency) and referral (transportation) package of PhilHealth.

7.1.1. The PhilHealth membership is already a guarantee for treatment even without deposit.

7.1.2. The classification of patients as to financial status for enrolment under Point of Service shall be certified by a duly licensed medical social worker of a government institution trained in DOH means tests. Whenever the patient has been provided care in a private institution, the patient shall be enrolled through the PhilHealth in the Point of Service Program in coordination with a government facility. Details for which shall be stipulated in the policy that will be issued by PhilHealth.

7.2. The Philippine Charity Sweepstakes Office (PCSO) shall provide medical assistance for the basic emergency care needs of the poor and marginalized groups. All patients managed for emergency cases and continuously admitted in the hospital shall be eligible for assistance from PCSO for the emergency care expenses following its guidelines of Endowment Fund Program and Individual Medical Assistance Program.
Section 8 - Tax Deductions

8.1. Basic emergency care to poor and indigent patients provided by the hospital or medical clinic not reimbursed by PhilHealth and PCSO shall be deductible from gross sales/receipts. The documentary requirements and details of mechanics on availment of the deduction shall be covered by a Revenue Regulation to be issued by the Bureau of Internal Revenue.

Section 9 - In order to demonstrate compliance with the provisions of R.A. no. 10932, all hospitals and medical clinics are instructed to institute the following measures:

9.1. Display a copy of the law and its implementing rules and regulations prominently in all hospital emergency rooms, hospital admission counters and medical clinic premises;

9.2. Have their hospital and clinic managers instruct their personnel to provide prompt and immediate medical attention to emergency and serious cases without any prior requirements for payment or deposit;
Section 5 of R.A. No. 10932 mandates the creation of a Health Facilities Oversight Board, which shall receive all the complaints filed against health facilities violating this Act. The members of the Board are as follows:

**CHAIRPERSON:**
ROLANDO ENRIQUE D. DOMINGO, M.D., MSc
Undersecretary of Health, Office for Health Regulation

**VICE-CHAIRPERSON:**
ATTY. ROMELA D. DEVERA, CPA
Director IV, Legal Service
MEMBERS:

1. ATTY. NICOLAS B. LUTERO III, CESO III - Director IV, HFSRB
2. ATTY. RODEL C. FLORES - Chief, Regulation Compliance and Enforcement Division, HFSRB
3. DR. TEODORA M. EUGENIO - Chief, Quality Assurance and Monitoring Division, HFSRB
4. PRESIDENT AND CHIEF EXECUTIVE OFFICER/ OFFICIAL REPRESENTATIVE - PHIC
5. PRESIDENT/OFFICIAL REPRESENTATIVE - PMA
6. PRESIDENT/OFFICIAL REPRESENTATIVE - PHA
7. PRESIDENT/OFFICIAL REPRESENTATIVE* - Philippine Alliance of Patient Organization
8. PRESIDENT/OFFICIAL REPRESENTATIVE* - Medical Action Group
9. PRESIDENT/OFFICIAL REPRESENTATIVE* - Philippine Alliance of Persons with Chronic Illness

*At least one representative from either of the three organization is a medical director.
DPO No. 2017-5746: Creation of Health Facilities Oversight Board

Signed: December 15, 2017

Technical Secretariat: RCED- Complaints and Action Unit (CAU), HFSRB

1. DR. ROSENDO SUALOG - Medical Specialist III
2. MS. ALICE BAQUIRAN - Licensing Officer III
3. MS. EDELYN ORILLO - Licensing Officer II
4. MR. GLENN CARO - Administrative Assistant II
Functions of the Board:

1. Investigate the claim of the patient through a fact-finding investigation.
2. After adjudication, impose administrative sanctions in accordance with R.A. 10932, including the revocation of health facility’s license.
3. Facilitate the filing of the criminal case in the proper courts.
4. The board may invite other experts from specialty societies if the need arises.
REVISED ASSESSMENT TOOL FOR LICENSING A HOSPITAL
Department Circular No. 2018-0131 dated April 11, 2018
Revised Licensing Assessment Tool for Hospitals

Based from the review of the draft hospital assessment tools and discussions during Technical Working Group meetings, Bimonthly Regulatory Licensing and Enforcement Division Chiefs Meetings, National Dialogue, and consultative meetings with HFSRB technical staff and specialty societies, the assessment tool for licensing of hospitals and infirmaries have been revised. The licensing standards and requirements are aligned with the provisions of Administrative Order No. 2012-0012 and its amendments.
• The Hospital Assessment Tool for licensing a hospital was divided into parts:
  a. Part I: Standards for Medical Services
  b. Part II: Standards for Nursing Services
  c. Part III: Standard for Physical Plant
  d. Part IV for Level I Hospital
     i. Attachment 1.A. - Personnel
     ii. Attachment 1.B. - Physical Plant
     iii. Attachment 1.C. - Equipment/Instruments
     iv. Attachment 1.D. - Emergency Cart Contents for Level 1 Hospitals
     v. Attachment 1.E. - Add-on Services
What are the Major Changes?

e. Part IV for Level I Hospital
   i. Attachment 2.A. - Personnel
   ii. Attachment 2.B. - Physical Plant
   iii. Attachment 2.C. - Equipment/Instruments
   iv. Attachment 2.D. - Emergency Cart Contents for Level 2 Hospitals

f. Part IV for Level I Hospital
   i. Attachment 3.A. - Personnel
   ii. Attachment 3.B. - Physical Plant
   iii. Attachment 3.C. - Equipment/Instruments
What are the Major Changes?

• The HFSRB-approved floor plan shall be the basis for assessing compliance to the licensing standards for physical plant during inspection or monitoring.

• The required quantity for each emergency medicine has been removed from the Assessment Tool. Hence, the hospitals and infirmaries have the sole responsibility for ensuring the availability of the emergency medicines based on their clinical practice guidelines or protocol and frequency of usage.
What are the Major Changes?

• Additional licensing requirements include compliance to:
  • Implementation of the Electronic Medical Records
  • Implementation of the Antimicrobial Stewardship
  • National laws and DOH issuances:
    • RA No. 10932: Anti-Hospital Deposit Law
    • EO No. 26 s. 2017: Providing for the Establishment of Smoke-Free Environments in Public and Enclosed Places
    • AO No. 2007-0041: Guidelines on the Mandatory Allocation of a Certain Percentage of the Authorized Bed Capacity as Charity Beds in Private Hospitals
    • RA No. 9439: An Act Prohibiting the Detention of Patients in Hospitals and Medical Clinics on Grounds of Nonpayment of Hospital Bills or Medical Expenses
What are the Major Changes?

• National laws and DOH issuances (continuation):
  • RA 10173: An Act Protecting Individual Personal Information in Information and Communications Systems in the Government and the Private Sector, Creating for this Purpose a National Privacy Commission, and for Other Purposes
  • Act No. 3753: Law on Registry of Civil Status
  • Presidential Decree No. 766: Amending Sections 2 and 5 of Presidential Decree No. 651, entitled “Requiring the Registration of Births and Deaths in the Philippines which occurred from January 1, 1974 and thereafter” and extending the Period of Registration up to December 31, 1975

• The revised Assessment Tools for hospitals to be used for both inspection and monitoring shall be effective starting April 23, 2018.
A.O. No. 2018-0016
ONE-STOP SHOP ONLINE LICENSING SYSTEM
A.O. No. 2018-0016
ONE-STOP SHOP ONLINE LICENSING SYSTEM

• IDLIS (INTEGRATED DOH LICENSING INFORMATION SYSTEM)

• OLRS (ONLINE LICENSING AND REGULATORY SYSTEM)
  • CON, PTC, OSSOLS (LTO/COA)

• KMITS project with INFO ADVANCE: Feb 2018

• A.O. 2007-0021: HARMONIZATION AND STREAMLINING OF THE LICENSURE SYSTEM FOR HOSPITALS

• OHR and DAP (Innovation Laboratory)
A.O. No. 2018-0016
ONE-STOP SHOP ONLINE LICENSING SYSTEM

System Features

- Access anytime & anywhere
- Real-time Checking of Status
- Secured account & transaction
- Online Schedule of Inspection
- Online Encoding and Submission of Documents
- Mapping Geographical Coordinates
- Options for Mode of Payment
- Intuitive Alerts for Users
What is One-Stop-Shop 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.
Section V. Implementing Mechanism
A.O. No. 2018-0016
ONE-STOP SHOP ONLINE LICENSING SYSTEM

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.
A.O. No. 2018-0016
ONE-STOP SHOP ONLINE LICENSING SYSTEM

7. The HFSRB/RO-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.

e) The application will not proceed if there are incomplete entries and lacking documentary requirements.

f) Once the application is accepted into the system, the assigned OSS evaluators shall assess the technical correctness of the documentary requirements submitted including proofs of payment. A technically correct application means that the required documents, as specified in the application checklist of HFSRB/RO-RLED and FDA, have been submitted. The timeline from acceptance to approval of application is three (3) days.
g. If the application was evaluated to be technically incorrect, a system generated email will be sent automatically to the applicant, and the status of the application shall appear as “WITH DEFICIENCY”. A STOP-CLOCK shall be observed and the client shall be given thirty (30) days to correct the documentary requirements. Failure to do so shall result in the DISAPPROVAL and forfeiture of payment.

h. If the application was evaluated to be technically correct, HFSRB/RO-RLED and FDA shall organize a team of inspectors and shall implement joint inspections of health facilities whose priority are those under the One-Stop Shop Licensing System. From the time of approval of the application, the inspection teams from HFSRB/RO-RLED, RFO and CDRRHR/RFO shall be given twenty (20) days to inspect the facility.
i. Inspection maybe waived by RFO, who shall then automatically issue a Recommendation Letter (RL) for pharmacy and schedule a post licensing inspection. Nevertheless, if deemed necessary, the RFO may conduct an inspection of the pharmacy and shall then transmit the COC online to HFSRB/RO-RLED, if compliant. A copy of the Inspection Report shall be issued to the facility. The list of facilities found to be non-compliant during the post licensing inspection shall be forwarded to HFSRB/RO-RLED.

j. If found non-compliant during inspection, the inspection team from the concerned offices shall notify the applicant of their deficiencies and the facility shall be given time to comply within the prescribed timeline (maximum of 30 days).

k. The counting of days for the HFSRB/RO-RLED to process the application shall be stopped (“STOP-CLOCK”) until all deficiencies have been complied with.
l. Failure to complete the compliance within the timeline given shall mean disapproval of the application and forfeiture of payment. The client shall then be notified through e-mail, and shall have to re-apply.

m. For compliant health facilities, the following documents shall be transmitted online to HFSRB/RO-RLED:
   i. For Hospital, Infirmary
      From CDRRHR/RFO: COC for Levels I, II and III diagnostic x-ray facilities, dental x-ray facilities, interventional and specialized x-ray facilities; Certificate of Registration for Magnetic Resonance Imaging (MRI) facilities; and LTO for Transportable X-ray Facility and for Therapeutic X-ray Facility Utilizing Medical Linear Accelerator (LINAC) x-ray machines

   From RFO: RL/COC for pharmacy
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ii. For Birthing Home, ASC, MFOWS, Dialysis Clinic

   From CDRRHR/RFO: COC for diagnostic radiology
   From RFO: RL/COC for pharmacy

n. The assigned OSS evaluators from HFSRB/RO-RLED, after receiving the transmitted RL/COC from RFO, and COC, COR or LTO from CDRRHR/RFO, shall then recommend to the Director IV of HFSRB/RO Director, or in his/her absence or unavailability or when delegated, the Director III of HFSRB/RO, the approval of the issuance of the DOH-LTO or DOH-COA.
The Director IV of HFSRB/RO Director, or in his/her absence or unavailability or when delegated, the Director III of HFSRB/RO, shall approve the issuance of the DOH-LTO or DOH-COA.

The system will then generate a hard copy of the DOH-LTO or DOH-COA on a security paper with QR (quick response) code, to be picked up by the applicant or be delivered by courier, depending on the chosen method of delivery.

Once licensed, applicant shall be assigned a National Health Facility Registry Code as its new username and a system generated password for DOH-LTO/DOH-COA renewal and shall be transmitted via email.

The timeline from complete compliance after inspection to the issuance of DOH-LTO/DOH-COA shall be seven (7) days.
s. The timeline for the issuance of the initial DOH-LTO or DOH-COA shall be within thirty (30) days from acceptance of complete application.

t. If due to force majeure or any unforeseen events, the RL/COC/COR/LTO from FDA and DOH-LTO or DOH-COA were not issued within the 30-day period from receipt of the complete application, the DOH-LTO or DOH-COA shall automatically be issued, but a post licensing inspection shall be undertaken by the concerned offices.
2. Renewal of the License or Accreditation  
(See Annex B for the Process Flow of Renewal Application)

a) The renewal period for DOH-LTO or DOH-COA shall be from October 1 to December 15 of the current year. A 10% discount shall be given to those who filed complete renewal applications from October 1 to November 30 of the current year.

b) Application to HFSRB/RO-RLED and FDA (RFO and CDRRHR) shall be through the OLRS, using the National Health Facility Registry code assigned to the licensed health facility as username and the system generated password.

c) The timeline for automatic renewal shall be fifteen (15) days from acceptance into the system of the complete application forms, together with the other documentary requirements and the uploaded scanned copy of the proofs of payment for each office, to the issuance of DOH-LTO/DOH-COA.
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ONE-STOP SHOP ONLINE LICENSING SYSTEM

d.) Eligible for automatic renewal:
   i. facilities with no sanctions, violations or deficiencies;
   ii. facilities which have corrected/complied to the noted violations at the time of application; and
   iii. facilities which submitted/participated in the Online Health Facility Statistical Reporting System (OHFSRS)

e.) Automatic renewal shall only apply to hospitals.

f.) The DOH-LTO or DOH-COA of those facilities with sanctions, violations or deficiencies shall be renewed only after serving out their sanction/penalty or corrected their violations, or completed their deficiencies. If compliance was met after the expiration of the DOH-LTO/DOH-COA, the date of validity of the new DOH-LTO/DOH-COA shall start from the date of full compliance.
g.) HFSRB shall conduct monitoring visits and FDA (RFO and CDRRHR) may carry out Post Licensing Inspection on those facilities which renewed their DOH-LTO/DOH-COA automatically, and those with previous sanctions or violations.

h.) Whenever there are changes in the circumstances of the facility, such as, but not limited to, change of ownership, transfer of site, and increase in bed, the health facility shall go through the same process in the issuance of initial DOH-LTO or DOH-COA.

i.) Sanctions for late filing of application for renewal of DOH-LTO or DOH-COA shall be in accordance with the existing rules and regulations of the concerned bureau/agency.
SECTION VI.
Validity of DOH-LTO or DOH-COA

a) The DOH-LTO for the hospitals, birthing homes and infirmaries shall be valid for one (1) year.

b) The DOH-LTO for non-hospital-based dialysis clinics and non-hospital-based ambulatory surgical clinics shall be valid for three (3) years.

c) The DOH-COA for the non-hospital-based medical facilities for overseas workers and seafarers shall be valid for three (3) years.
a. The DOH-LTO or DOH-COA fee shall follow the Schedule of Fees currently prescribed by the DOH and FDA.

b. The applicant, upon filing the application, shall pay the corresponding fee to the DOH/RO Cashier and FDA Cashier or any authorized banks for pharmacy and diagnostic radiology and radiation oncology.
Imposable penalties for violations hereof shall be in accordance with A.O. No. 2007-0022 titled “Violations under the One-Stop Shop Licensure System for Hospitals”, 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”, and related issuances or guidelines.
SECTION IX. APPEAL

Any hospital or other health facility aggrieved by the decision of the Director IV of HFSRB/RO Director, or in his/her absence or unavailability or when delegated, the Director III of HFSRB/RO, or FDA Director-General may, within ten (10) days after receipt of the notice of decision file a notice of appeal to the Head of the Office for Health Regulation (OHR). All pertinent documents and records of the applicant shall then be elevated by the HFSRB or RO to the OHR. The decision of the Head of the OHR if still contested maybe brought on a final appeal to the Secretary of Health whose decision shall be final and executory.
SECTION X.
TRANSITORY PROVISIONS
## Implementation of the OSS Licensing System shall be done by phase:

<table>
<thead>
<tr>
<th>Phase 1 (Central Office)</th>
<th>Phase 2 (Central/Regional Offices)</th>
<th>Phase 3 (Full Implementation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• July 2018</td>
<td>• July 2019</td>
<td>• July 2020</td>
</tr>
<tr>
<td>• initial DOH-LTO of hospitals</td>
<td>• initial DOH-LTO of hospitals</td>
<td>• initial/renewal of the DOH-LTO/DOH-COA of all health facilities under the OSS Licensing System</td>
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<td>• initial DOH-LTO/DOH-COA of other health facilities</td>
<td>• renewal of DOH-LTO of hospitals in selected regions</td>
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<td>• initial and renewal of the DOH-LTO/DOH-COA of other health facilities</td>
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2. The OSS Licensing System shall be implemented even while the online system is being developed and finalized.

3. The General Guidelines and the Specific Guidelines for Initial and Renewal of DOH-LTO/DOH-COA (Section V. A and B of this A.O.) shall be applicable during the transition period. Submission of documentary requirements including the copy of the proofs of payment to HFSRB/RO-RLEDs shall be in hard copies, while those for FDA shall be in hard copies and soft copies saved in universal serial bus (USB) flash drive. The processing of the complete application forms and documentary requirements shall be done manually.
4. The HFSRB/RO-RLED and FDA shall designate OSS Evaluators who shall assess the completeness and technical correctness of the submitted documents.

5. The same timelines shall be observed for all processes (initial/renewal) as stated in Section V. A and B.
SECTION XIII.
REPEALING CLAUSE
REPEALING CLAUSE

This repeals/revokes A.O. No. 2007-0024 known as Guidelines for the Licensure of Department of Health Hospitals and A.O. No. 2008-0027 titled One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Based Ambulatory Surgical Clinics with Ancillary Services.

Provisions from previous issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded and modified accordingly.
In the event that any provision or part of this Order is declared unconstitutional or null and void and rendered invalid by any court of law of competent authority, those provisions not affected by such declaration shall remain valid and effective.
This Order shall take effect fifteen (15) days after its approval and publication in the official gazette or two (2) newspapers of general circulation.
Process Flow of One-Stop-Shop Licensing System (RENEWAL)
ONE-STOP SHOP LICENSING SYSTEM PROCESS FLOW
AUTOMATIC RENEWAL

TIME TABLE
PERSON/S RESPONSIBLE

Step 1: Applicant shall log in using the National Health Facility Registry code assigned to the LICENSED health facility and the system-generated password

Applicant

Step 2: Applicant shall encode and/or upload the documentary requirements including scanned copy of the proofs of payment for HFSRB/RO-RLED and FDA

Incomplete Entries

Application will not proceed to Step 3

Complete Entries

Step 3: Assigned OSS evaluator shall assess the technical correctness of the documentary requirements submitted including proofs of payment

OSS EVALUATORS (HFSRB/RO-RLED, FDA)

Within three (3) days
Note: For those applicants that are not eligible for automatic renewal, the timeline for issuance of DOH-LTO/DOH-COA shall follow the initial application process.
Process Flow of One-Stop-Shop Licensing System (INITIAL)
ONE-STOP SHOP LICENSING SYSTEM PROCESS FLOW

**INITIAL**

**STEPS:**

1. **Applicant** shall create an account at the OLRS webpage.
   - Once registered, the applicant may log in to access and fill out the application forms for HFSRB/RO-RLED and FDA.

2. **Applicant** shall encode and/or upload the documentary requirements including scanned copy of the proofs of payment for HFSRB/RO-RLED and FDA.

   - **Incomplete Entries:** Application will not proceed to Step 3
   - **Complete Entries:**
     - Step 3: Assigned OSS evaluators shall assess the technical correctness of the documentary requirements submitted including proofs of payment.
       - **Technically Incorrect**
       - **Technically Correct**

**TIME TABLE**

- **OSS EVALUATORS (HFSRB/RO-RLED, FDA):**
  - Within three (3) days

**PERSON/S RESPONSIBLE**
STOP-CLOCK shall be observed (maximum of 30 days to comply)*
Status of application will be sent automatically to the applicant via system generated e-mail
Failure to comply within 30 days shall result to DISAPPROVAL and forfeiture of payment

If applicant complied within 30 days, proceed to Step 4

STOP-CLOCK shall be observed (maximum of 30 days to comply)*
Inspection team shall notify the applicant of their deficiencies and the facility shall be given time to comply within the prescribed timeline

Non-Compliant

Compliant

Step 4: HFSRB/RO-RLED and FDA shall implement joint inspection of the health facility

Within twenty (20) days

Step 5: The following documents shall be transmitted online to HFSRB/RO-RLED:

a) CDRRHR/RFO (diagnostic radiology and radiation oncology): COC/COR/LTO
b) RFO (pharmacy): RL/COC

OSS EVALUATORS HFSRB/RO-RLED, FDA
Note: Once licensed, applicant shall be assigned a National Health Facility Registry Code as its new username and a system generated password for DOH-LTO/DOH-COA renewal and shall be transmitted via email.

*The counting of days shall be stopped ("STOP-CLOCK") until all deficiencies have been complied with.
HFSRB Contact Information

- **HFSRB EMAIL**: hfsrb@doh.gov.ph

- **Standards Development Division (SDD)**:
  - Trunk line: 651-7800 local 2525

- **Quality Assurance and Monitoring Division (QAMD)**:
  - Trunk line: 651-7800 local 2528

- **Regulatory Compliance and Enforcement Division (RCED)**:
  - Trunk line: 651-7800 local 2511
Thank you!