



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

October 19, 2017

DEPARTMENT MEMORANDUM

No. 2017- 0425

FOR: ALL DIRECTORS OF THE REGIONAL OFFICES, CHIEFS OF THE REGULATION, COMPLIANCE AND ENFORCEMENT DIVISION (RCED) AND OF THE REGULATION, LICENSING AND ENFORCEMENT DIVISION (RLED) AND REGULATORY OFFICERS

SUBJECT: Clarification on the Certificates Issued by the Food and Drug Administration Prior to the Issuance of a License to Operate a Hospital in the One Stop Shop Strategy

The One Stop Shop (OSS) Strategy, based on Administrative Order No. 2007-0021: Harmonization and Streamlining of the Licensure System for Hospitals, requires applications for the ancillary services, like Pharmacy and X-ray, be submitted together with the application for License to Operate (LTO) a Hospital to the Health Facilities and Services Regulatory Bureau (HFSRB) or at the Regional Office –Regulation, Licensing and Enforcement Division (RO-RLED). The applications shall be forwarded to the Food and Drug Administration (FDA), specifically to the Regional Field Office of the Center for Drug Regulation and Research (RFO/CDRR) for Pharmacy and to the Center for Device Regulation, Radiation Health and Research (FDA CDRRHR) for X-ray. FDA shall then submit to HFSRB/RO-RLED the Certificates of Compliance of the compliant facility prior to the issuance of the LTO.

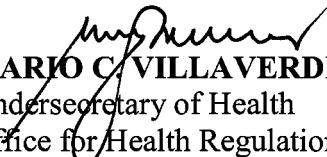
The following shall serve as a guide to the specific FDA certificate requirement/s for the issuance of the LTO:

Concerned FDA Office	Certificate/s submitted to HFSRB/RO-RLED	Certificate issued to the facility
RFO/CDRR for Pharmacy	*Recommendation Letter for initial LTO waived Inspection	Inspection Report
	*Certificate of Compliance for Inspected facilities	
CDRRHR for X-ray	*Recommendation Letter for waived Inspection.	Inspection Report
	*Certificate of Compliance for Inspected Diagnostic X-ray facilities, interventional and specialized X-ray facilities	
	*Certificate of Registration for Magnetic Resonance Imaging (MRI) Facilities	
	*License to Operate for Transportable X-ray Facility and for Therapeutic X-ray Facility utilizing Medical Linear Accelerator (LINAC)	

Furthermore, FDA shall furnish HFSRB/RO-RLED updated list of facilities found to still be non-compliant even after the 30 day grace period given, so that appropriate action can be taken.

For strict compliance.

By Authority of the Secretary of Health:


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Undersecretary of Health
Office for Health Regulation