Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary

BAGONG PILIPINAS

July 1, 2025

DEPARTMENT CIRCULAR
No. 2025- 0291

FOR : **FDA DIRECTOR GENERAL, FDA DEPUTY DIRECTOR GENERAL OF FIELD REGULATORY OPERATIONS OFFICE, FDA CLUSTER HEADS, DIRECTORS OF CENTER FOR DRUG REGULATION AND RESEARCH (CDRR) AND CENTER FOR DEVICE REGULATION RADIATION HEALTH AND RESEARCH (CDRRHR), FDA SUPERVISORS OF REGIONAL FIELD OFFICES; DIRECTOR OF HEALTH FACILITIES AND SERVICES REGULATORY BUREAU (HFSRB); DIRECTOR OF KNOWLEDGE MANAGEMENT INFORMATION TECHNOLOGY SERVICE (KMITS); DIRECTORS OF CENTERS FOR HEALTH DEVELOPMENT (CHD); CHIEFS OF CHD-REGULATION LICENSING AND ENFORCEMENT DIVISION (RLED) AND HEALTH REGULATION DIVISION OF BARMM; AND REGULATORY OFFICERS AND ALL OTHERS CONCERNED**

SUBJECT : **Interim Guidelines on the Application Process for Health Facilities, X-ray Services, and Pharmacies Through the Online Licensing and Regulatory System (OLRS)**

Department Circular No. 2023-0375 titled "Deferment of Online Licensing and Regulatory System (OLRS) Implementation in Pilot Offices (Centers for Health Development Metro Manila, Central Luzon, CALABARZON, and MIMAROPA)" mandates the continued operation of the Online Licensing and Regulatory System (OLRS) by the Health Facilities and Services Regulatory Bureau (HFSRB), effective August 1, 2023. This is a collaborative effort with the Knowledge Management and Information System (KMITS), the primary objective of which is to augment the efficiency of crucial frontline services and automate licensing and regulatory processes.

Since implementation began, the system's functionalities have been tested and additional modules integrated, such as x-ray and pharmacy services for the Center for Device Regulation, Radiation Health and Research (CDRRHR) and Center for Drug Regulation and Research (CDRR), respectively. A key challenge in migrating the x-ray module involves managing complex initial and variation applications in existing health facilities. This includes the type of equipment, corresponding payments, inspection process, and validity periods that cannot be accommodated by the system's current design.

Likewise, the pharmacy module experiences critical problems for variation applications that could be resolved in the Phase II development of the OLRS. Thus, system modification is necessary to accommodate changes that would meet the functional requirements for specific service processes such as x-ray and pharmacy ancillaries.

Pending the completion of the FDA modules, the following guidelines shall be observed starting **July 15, 2025:**

I. **Application Guidelines for X-ray Facilities in Health Facilities under the FDA-CDRRHR**

A. Application Process

1. Application process shall be in accordance with the type of application, the services capability, and the location of the facility
2. X-ray facilities under One-Stop Shop Health Facilities shall submit their X-ray application through HFSRB OLRS and/or FDA CDRRHR email address at cdrrhr.rrd@fda.gov.ph:

Service Capability	Region	Type of X-ray Application	HFSRB OLRS	FDA-CDRRHR
Level 1 Hospital	All Regions	Initial		√
		Renewal		√
		Variation		√
Level 2 Hospital	CARAGA and BARMM	Initial	√	√
		Renewal	√	√
		Variation		√
	Regions II, III, IV-A, IV-B, V, VI, VII, VIII, IX, X, XI, XII, CAR, NCR and NIR	Initial		√
		Renewal		√
		Variation		√
Level 3 Hospital	Regions I, II, and III	Initial		√
		Renewal		√
		Variation		√
	Regions IV-A, IV-B, V, VI, VII, VIII, IX, X, XI, XII, CAR, NCR, NIR, CARAGA, BARMM	Initial	√	√
		Renewal	√	√
		Variation		√

Service Capability	Region	Type of X-ray Application	HFSRB OLRS	FDA-CDRRHR
Medical Facility for Overseas Workers and Seafarers (MFOWS)	All Regions	Initial	√	√
		Renewal	√	√
		Variation		√
Ambulatory Surgical Clinic	All Regions	Initial		√
		Renewal		√
		Variation		√
Dialysis Clinic	All Regions	Initial		√
		Renewal		√
		Variation		√
Infirmary	All Regions	Initial		√
		Renewal		√
		Variation		√
Primary Care Facility	All Regions	Initial		√
		Renewal		√
		Variation		√

A. Application Fees
   1. Application fee shall follow the current FDA Schedule of Fees and shall be paid to the FDA.

B. Application Results
   1. The results of initial and renewal applications submitted through the FDA-CDRRHR email shall be uploaded into the facility's corresponding application in the HFSRB OLRS.
   2. For facilities under the jurisdiction of the Center for Health Development (CHD) Regulation Licensing Enforcement Division (RLED), the Certificate of Compliance (COC) issued for both initial and renewal applications shall be sent to respective CHD RLED email addresses.
   3. For variation applications, the COC shall be endorsed to the HFSRB email at hfsrb@doh.gov.ph or to the respective CHD-RLED email addresses depending on the facility's jurisdiction.
   4. The authorization issued by the FDA shall serve as one of the bases for the HFSRB and the CHD RLED in issuing a single regulatory authorization.

II. Application Guidelines for Pharmacies in Health Facilities under the FDA-CDRR

A. Application Process for Ancillary Pharmacies
   1. Application process of ancillary pharmacies shall be according to their type of application, category, and location:

a. For Level 3 hospital pharmacies within the National Capital Region (NCR), applicants for initial and renewal shall resume submission of their applications through the HFSRB OLRS.
b. For Levels 1, 2, and 3 hospital pharmacies outside the NCR, applicants for initial and renewal shall continue to submit their applications with the Food and Drug Action Center (FDAC) via email, fdac.pacd@fda.gov.ph.
c. All modifications, amendments, or variations in their existing LTO shall also be submitted to the email address of FDAC (fda.pacd@fda.gov.ph) for all regions.

B. Application Forms and Fee

1. Applicants of initial, renewal, and variation from Levels 1, 2, and 3 hospital pharmacies outside the NCR must use the Modified Application Form (MAF), which can be accessed through the FDA eServices Portal System (https://eservices.fda.gov.ph)

2. The restructured application fee is reflected in Annex C of Administrative Order No. 2024-0016, entitled "Implementing Guidelines on the New Schedule of Fees and Charges of the Food and Drug Administration."
The fee is Php 3,000 annually plus 1% Legal Research Fund. The annual fee shall be multiplied by the allowable number of years of validity.

In the event of a suspension of the fees set forth under Administrative Order No. 2024-0016, the applicable application fee shall revert to those prescribed under Administrative Order No. 50 s. 2001, for all applications affected by such suspension.

C. Validity of License to Operate of Pharmacy

1. The validity of a License-to-Operate (LTO) based on Administrative Order No. 2024-0015, entitled "Prescribing the Rules, Requirements and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017", depends on the declared capital of the hospital.
2. Micro and Small Enterprises with not more than Php3M and 15M capital, respectively, shall have a 3-year validity for initial LTO and 6 years for renewal LTO
3. Medium Enterprises with not more than Php 100M capital shall have a 6-year validity for initial LTO and 12 years for renewal LTO.
4. Large Enterprises with more than 100M capital shall also have a 6- year validity for initial LTO and 12 years for renewal LTO.

III. Application Process for Hospital License to Operate (LTO) under DOH-HFSRB and CHD RLEDs

Applicants for a Hospital License to Operate (LTO) shall continue to follow the established procedures for application submission, which varies depending on the hospital level and location.

A. Level 1 Hospitals
Level 1 Hospital applications shall be submitted through the existing process via their respective CHD RLEDs

B. Level 2 Hospitals
Level 2 Hospital applicants from CARAGA and the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) shall resume submitting their applications through the HFSRB OLRS.

Level 2 Hospital applications in other regions, aside from CARAGA and BARMM, shall be submitted through the existing process via their respective CHD RLEDs

C. Level 3 Hospitals
Level 3 Hospital applications in all regions shall continue to be submitted through the HFSRB OLRS, except in Regions I, II, and III where applications shall follow the existing process via their respective CHD RLEDs.

Applications for selected add-on service/s in an existing Level 3 hospital under the jurisdiction of HFSRB shall submit their applications at the HFSRB Office or email at hfsrb@doh.gov.ph with an accomplished Application Form 2, documentary requirements, and payment (as applicable).

IV. Issuance of FDA Certificate of Compliance (COC) and Recommendation Letter (RL)

A. The workaround module developed for X-ray applications shall remain in use until the full integration of the new FDA system is completed.

B. Similarly, the results of FDA inspections or desktop evaluations for Hospital Pharmacy applications shall continue to serve as the basis for issuing a Certificate of Compliance (COC) or Recommendation Letter (RL), respectively.

C. To ensure efficient and seamless processing, the results of the affected applications shall be uploaded to the OLRS, allowing the HFSRB to issue a single regulatory authorization under the One-Stop Shop Licensing System.

Please be guided accordingly.

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