Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

APR 14 2021

ADMINISTRATIVE ORDER
No. 2021- 0029

SUBJECT: Guidelines on the Prioritization of Processing of Applications for DOH Authorizations of Health Facilities Located in GIDAs in the Philippines

I. RATIONALE

Due to the archipelagic and geographic landscape of the country, patients experience difficulty in accessing safe and quality health facilities, more so in geographically isolated and disadvantaged areas (GIDAs). It is imperative for the government to respond to the needs of these communities by ensuring seamless delivery of health goods and services. A strategy to strengthen the health system in GIDAs is to strike a balance between maintaining safe and quality health services through compliance of health facilities with DOH licensing standards and establishment of a facilitative regulatory process.

Considering the importance and urgency of establishing health facilities in GIDAs, Section 29.3 of the Implementing Rules and Regulations of the Universal Health Care Act mandates that "The DOH shall develop a system to prioritize the processing of applications and issuance of License to Operate and Certificate of Accreditation for health facilities in these areas."

Therefore, this Order is being issued to provide guidelines for the prioritization of processing of DOH authorizations in GIDAs. It aims to encourage and facilitate establishment of health facilities in GIDAs by improving ease of regulatory transactions with the Health Facilities and Services Regulatory Bureau (HFSRB), the Center for Health Development – Regulatory Licensing and Enforcement Divisions (CHD-RLEDs) and Food and Drug Administration. It centers on streamlined and efficient regulatory processes while maintaining the same licensing standards to ensure safety and quality of services in health facilities.

II. OBJECTIVES

This Order aims to set the guidelines in prioritizing the processing of applications for DOH authorizations of health facilities located in GIDAs.

III. SCOPE

This Order shall apply to all newly established and/or unlicensed government and private health facilities located in GIDAs, and to HFSRB, CHD-RLEDs, Food and Drug Administration (FDA), and Philippine Nuclear Research Institute (PNRI).

In the case of Bangsamoro Autonomous Region in Muslim Mindanao (BARMM), the adoption of this Order shall be in accordance with the applicable provisions of RA 11054 or the "Bangsamoro Organic Act" and subsequent rules and policies issued by the Bangsamoro government.

IV. DEFINITION OF TERMS

A. Applicant – the natural or juridical person who is applying for a License to Operate or Certificate of Accreditation of a hospital or any other health facility.

B. Department of Health Authorizations (DOH Authorizations) – a formal authority issued by DOH, such as, but not limited to, DOH-LTO, DOH-COA and DOH-PTC.

C. Department of Health – Certificate of Accreditation (DOH-COA) – refers to the formal authorization issued by DOH to an individual, partnership, corporation or association to operate a health facility. It refers to compliance to standards set for a particular purpose such as, but not limited to, HIV testing, drug testing, water analysis, issuance of medical fitness certification to overseas work applicants, and performance of kidney transplant. These standards cover input/structural, process and outcome/output standards.

D. Department of Health – Certificate of Need (DOH-CON) - a required document prior to the issuance of a DOH – Permit to Construct of new government and private hospital.

E. Department of Health - License to Operate (DOH-LTO) – a formal authority issued by DOH to an individual, agency, partnership or corporation to operate a hospital or other health facility.

F. Department of Health – Permit to Construct (DOH-PTC) – a permit issued by DOH through HFSRB to an applicant who will establish and operate a hospital or other health facility, upon compliance with required documents prior to the actual construction of the said facility. A DOH-PTC is also required for hospitals and other health facilities with substantial alteration, expansion, renovation, increase in the number of beds, transfer of site, or for additional services (add-ons) beyond their service capability. It is a prerequisite for License to Operate.

G. Geographically Isolated and Disadvantaged Areas (GIDAs) – refer to barangays which are specifically disadvantaged due to the presence of both physical and socio-economic factors (DOH AO No. 2020-0023).

H. Health Facility – refers to institution, whether stationary or mobile, land based or otherwise, that provides healthcare and other health-related establishment which provides diagnostics, therapeutic, rehabilitative, palliative and/or related health care services except medical radiation facilities and hospital pharmacies.

I. Initial Applications – refer to applications by newly constructed health facilities, changes in the circumstances of the facility, such as, but not limited to, change of ownership, transfer of site, and increase in bed and major alterations or renovations.

J. One-Stop Shop (OSS) 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

K. Philippine Nuclear and Research Institute (PNRI) - an agency under the Department of Science and Technology (DOST) that was created by virtue of R.A. No. 2067 to promote the peaceful uses of atomic energy and promulgate rules and regulations to ensure the safe use and application of radioactive materials in the different fields of application.

V. GENERAL GUIDELINES

A. All health facilities that shall be established in GIDAs must secure a Department of Health – Permit to Construct (DOH-PTC), Department of Health – License to Operate (DOH-LTO) or Department of Health – Certificate of Accreditation (DOH-COA), whichever is applicable, and must be compliant at all times with the licensing standards and requirements set forth by the Health Facilities and Services Regulatory Bureau (HFSRB), Food and Drug Administration (FDA), and Philippine Nuclear Research Institute (PNRI), when applicable.

B. A priority lane shall be established for applicants from areas that are included in the DOH official list of GIDAs, in accordance with Administrative Order (AO) No. 2020-0023, titled "Guidelines on Identifying Geographically-Isolated and Disadvantaged Areas and Strengthening their Health Systems." All applications for DOH authorizations from GIDAs shall be prioritized through the priority lane for processing and issuance by the HFSRB, CHD-RLEDs and Ministry of Health - Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM).

C. The Certificate of Need (CON) shall not be a prerequisite for the issuance of DOH-PTC and DOH-LTO of hospitals to be established in GIDAs.

D. The DOH-PTC, when applicable, shall remain a prerequisite for the issuance of DOH-LTO or DOH-COA.

E. All applications shall be processed manually or through the Online Licensing and Regulatory System (OLRS), once the online system is fully functional.

F. Applicants from GIDAs shall adhere to the timelines of application period and annual cut-off dates stipulated in AO No. 2019-0004, titled, "Guidelines on the Annual Cut-off Dates for Receipt of Complete Applications for Regulatory Authorizations Issued by the Department of Health."

G. The processing timelines for the DOH authorizations shall be in accordance with the RA No. 11032, also known as "Ease of Doing Business and Efficient Government Service Delivery Act of 2018."

VI. SPECIFIC GUIDELINES

A. Pre-evaluation of Health Facilities in GIDAs

1. The HFSRB/CHD-RLEDs/MOH-BARMM, in partnership with the Provincial Department of Health Office (PDHO), shall conduct information dissemination and orientation activities regarding regulatory processes of health facilities in GIDAs.
2. The HFSRB/CHD-RLED/MOH-BARMM shall provide, upon request, technical assistance to applicants regarding licensing standards and requirements of DOH-PTC and DOH-LTO/DOH-COA, prior to the filing of application.
3. Applicants shall self-evaluate their readiness to comply with the licensing standards using the appropriate Assessment Tool for the type of health facility they wish to apply for.

B. Application for DOH-PTC

1. Applications for DOH-PTC shall be filed with the appropriate regulatory office, in accordance with AO No. 2016-0042, titled "Guidelines in the Application for Department of Health - Permit to Construct (DOH-PTC)", until such time that the handling of applications for DOH-PTC of all levels of general hospitals, specialty hospitals, and other types of health facilities are transferred to the CHD-RLEDs and MOH-BARMM, in accordance with DOH guidelines.
2. The procedural guidelines for the evaluation and issuance of DOH-PTC, as well as the standard planning and design requirements, shall strictly follow the provisions of AO No. 2016-0042.
3. The Health Facilities Evaluation and Review Committee (HFERC) shall facilitate the immediate evaluation of valid applications through the priority lane.
4. The HFSRB/CHD-RLEDs/MOH-BARMM shall provide technical assistance to the applicants, as needed.

C. Application for DOH-LTO or DOH-COA

1. The guidelines for the One-Stop Shop Licensing implementation based on AO No. 2018-0016, titled "Revised Guidelines in the Implementation of the One-Stop Shop Licensing System", shall be strictly followed at the central, regional levels of the involved DOH regulatory offices, and MOH-BARMM, and processed by the appropriate regulatory office, until such time that the handling of applications for DOH-LTO and DOH-COA of all levels of general hospitals, specialty hospitals and other types of health facilities are transferred to the CHD-RLEDs and MOH-BARMM, in accordance with DOH guidelines.
2. The HFSRB/CHD-RLEDs/MOH-BARMM shall ensure that an inspection team is immediately assembled and an inspection activity is scheduled at the soonest possible date.
3. In case of inability of HFSRB/CHD-RLEDs/MOH-BARMM to conduct actual physical inspection due to extreme weather conditions, unavailability of transportation, time of calamity or disaster, declaration of quarantine, and other events that are beyond human control, a virtual inspection can be conducted, in accordance with Department Circular (DC) No. 2021-0006, titled "Guidelines in the Conduct of Virtual Inspection for the Initial

Licensing of Health Facilities". However, if virtual inspection is not possible due to unavailability or instability of internet connection, or other constraints in the conduct of virtual inspection, a DOH-LTO/DOH-COA shall be automatically issued to comply with the prescribed Anti-Red Tape Act (ARTA) timeline as soon as possible. The health facility shall be subjected to a post-licensing monitoring by the appropriate regulatory office. Violations noted during post-licensing monitoring, in accordance with the respective DOH regulatory policies, shall be corrected immediately by the health facility.

4. The HFSRB/CHD-RLEDs/MOH-BARMM shall ensure that the status of application, such as deficiencies and evaluation of compliance, is communicated immediately to the applicants.
5. Upon compliance to all licensing standards and requirements, HFSRB/CHD-RLEDs/MOH-BARMM shall prioritize the immediate approval and issuance of the DOH-LTO or DOH-COA.

D. Schedule of Fees

1. There shall be no processing fees for application of DOH authorizations of health facilities to be established in GIDAs.
2. Ancillary services, such as pharmacy and imaging facilities, shall be subjected to the FDA schedule of fees.

E. Validity of DOH Authorizations

1. The validity of DOH-PTC of health facilities located in GIDAs is two (2) years.
2. The validity of DOH-LTO and DOH-COA of health facilities shall be in accordance with the respective DOH issuances.

VII. ROLES AND RESPONSIBILITIES

A. Health Facilities and Services Regulatory Bureau

1. To disseminate regulatory policies, standards and forms for information and guidelines to the CHD-RLEDs and MOH-BARMM.
2. To provide technical assistance to stakeholders, including regulatory officers of CHD-RLEDs and MOH-BARMM.

B. Center for Health Development – Regulation, Licensing, and Enforcement Division (CHD-RLED) and Ministry of Health – Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM)

1. To strictly enforce the provisions of this Order.
2. To disseminate regulatory policies, standards and forms for information and guidelines to the Provincial Department of Health Offices (PDHOs) or counterpart agencies at the provincial level.
3. To provide technical assistance to stakeholders regarding regulatory requirements.

C. Food and Drug Administration (FDA)

To align its policy on prioritization of processing of licensing of ancillary services, such as pharmacy and imaging facilities that shall be established in

GIDAs, with the provisions of this Order and AO No. 2018-0016, titled "Revised Guidelines in the Implementation of the One-Stop Shop Licensing System."

D. **Philippine National Research Institute (PNRI)**

To align its policy on prioritization of processing of registration of radioactive materials in health facilities that shall be established in GIDAs.

E. **Bureau of Local Health Systems and Development (BLHSD)**

To provide the annual updated official GIDA list to HFSRB, CHD-RLEDs, and MOH-BARMM.

F. **Center for Health Development – Health Facility Development Unit (CHD-HFDU)**

To provide technical assistance to public institutions for the development of health facilities in accordance with the Philippine Health Facility Development Plan, aligned with existing licensing standards and requirements.

G. **DOH – Health Facility Enhancement Program**

To provide funding assistance for health facility enhancement and development to government applicants from GIDAs.

H. **Provincial Department of Health Office (PDHO)**

To facilitate dissemination of relevant DOH regulatory issuances and application forms to applicants in GIDAs.

VIII. REPEALING CLAUSE

Provisions from previous issuances that are inconsistent or contrary to this Order are hereby rescinded and modified accordingly. All other provisions of the aforementioned AOs which are not affected by this Order still stand in effect.

IX. EFFECTIVITY

This Order shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

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Secretary of Health