



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

FEB 18 2021

ADMINISTRATIVE ORDER

No. 2021 - 0019

SUBJECT : Guidelines in the Decentralization of Regulation of Levels 2, 3 General Hospitals and Specialty Hospitals to the Department of Health Center for Health Development-Regulation, Licensing and Enforcement Division

I. RATIONALE/BACKGROUND

Section 5 of Republic Act No. 4226, titled "An Act Requiring the Licensure of all Hospitals in the Philippines and Authorizing the Bureau of Medical Services to Serve as the Licensing Agency" or the Hospital Licensure Act, dated June 19, 1965, states that for the purpose of setting standards in hospital construction and operation, the Bureau of Medical Services (now Health Facilities and Services Regulatory Bureau) shall act as the licensing agency.

However, with the current COVID-19 pandemic and unavailable or limited means of transportation, the glaring need to have field offices to handle or resolve immediate problems is highlighted. Thus, it was decided in the 105th Regular Executive Committee Meeting held last December 15, 2020, that the regulatory authority of the Center for Health Development (CHD) needed to be strengthened and that the authority to regulate Levels 2, 3 general hospitals and specialty hospitals within their jurisdiction be permanently delegated to the CHDs. Hence, this policy to delegate to the CHD-Regulation, Licensing and Enforcement Division (RLED) the regulation of all levels of hospitals is hereby issued.

II. OBJECTIVES

These guidelines are being issued for a smooth transition or turn over in the regulation of Levels 2, 3 general hospitals and specialty hospitals from the Health Facilities and Services Regulatory Bureau (HFSRB) to the DOH CHD-RLED, without affecting the operations of the previously mentioned health facilities in the delivery of safe and quality health care.

Likewise, these guidelines will ensure the uniformity and consistency in the enforcement of regulation of the above-mentioned health facilities, with their ancillary and/or add-on facilities and services.

III. SCOPE OF APPLICATION

This Order shall apply to HFSRB, all DOH CHD-RLED and Levels 2, 3 general hospitals and specialty hospitals, their ancillary and/or add-on facilities and services.

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IV. DEFINITION OF TERMS

1. Applicant – refers to any natural juridical person, government instrumentalities/agencies, partnership, corporation or agency seeking a license to operate and to maintain a clinical laboratory.
2. Certificate of Need (CON) – a certificate, issued by DOH-CHD for the proposed construction of a new general hospital, which ensures that the facility will be needed at the time of its completion. The certificate is issued to an individual or group intending to build a hospital in order to meet the needs of a community. A CON is a required document prior to the issuance of a DOH-PTC for construction of a new general hospital.
3. DOH-License to Operate (DOH-LTO) – a formal authorization issued by the DOH through the Health Facilities and Services Regulatory Bureau (HFSRB) or DOH-CHDs to an individual, partnership, corporation or association seeking to operate a hospital or other health facility in compliance with the requirements prescribed in this Order.
4. 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.
5. Hospital – a place devoted primarily to the maintenance and operation of health facilities for the diagnosis, treatment and care of individuals suffering from illness, disease, injury or deformity or in need of obstetrical or other surgical, medical and nursing care. It shall also be construed as any institution, building or place where there are installed beds, cribs or bassinets for twenty-four hour use or longer by patients in the treatment of diseases.
6. 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.
7. One Stop Shop (OSS) Licensing System – a strategy of 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 clinics; 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 Ambulatory Surgical Clinics, non-hospital-based Dialysis Clinics, Infirmaries and Birthing Homes.
8. DOH-Permit to Construct (DOH-PTC) – a permit issued by DOH through HFSRB or CHDs to an applicant who will establish and operate a hospital or other health facility, upon compliance with required documents set forth in this Order prior to actual construction of the said facility. A DOH-PTC is also required for health facility with substantial alteration, expansion, renovation, etc. It is a prerequisite for DOH-LTO.

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V. IMPLEMENTING MECHANISMS

1. All hospitals, regardless of level, shall secure a DOH-License to Operate (LTO) from DOH CHD-RLED compliant to the licensing standards set forth by HFSRB and the Food and Drug Administration (FDA) at all times.
2. DOH-Permit to Construct (DOH-PTC) for Levels 2, 3 general hospitals and specialty hospitals shall be secured from the DOH CHD-RLED.
3. The implementation guidelines for the One Stop Shop Licensing System, whether manual or online, shall be strictly followed by the DOH CHD-RLEDs, FDA and the applicants.
4. The DOH-LTO of hospitals shall only be issued upon full compliance to the licensing standards and requirements set forth by the HFSRB and the FDA.
5. The Director IV of the DOH CHD shall approve the issuance of the DOH-LTO, upon the recommendation of the Chief of the RLED.
6. The guidelines set forth in the relevant DOH issuances (refer to Annex A) for each step in the application process shall strictly be followed by the DOH CHD-RLEDs and the applicants.
7. All facilities and services such as Kidney Transplant Unit, Medical Facility for Overseas Workers and Seafarers (MFOWS), and Human Stem Cell and Cell-Based or Cellular Therapy Facility located within the hospital premises currently licensed/accredited separately by HFSRB shall remain with HFSRB until such time that adequate human resource complement and capacity building of DOH CHD-RLED have been achieved.
8. All parties aggrieved by the decision of the DOH CHD-RLED on regulation of hospitals may file their appeal to the Office of the Secretary of Health (OSEC) in accordance with the OSEC's guidelines.
9. The Health Regulation Team through HFSRB shall exercise oversight, supervisory and monitoring functions over the DOH CHD-RLED with regard to the regulation of hospitals, their ancillary services and other health services.
10. The HFSRB shall exercise monitoring functions over all the hospitals and may recommend appropriate sanctions and penalties, if warranted.
11. The HFSRB shall provide technical assistance and capacity building to the DOH CHD-RLED with regard to the regulation of hospitals, their ancillary services and other health services.
12. DOH CHD-RLED shall submit to HFSRB the following:
 - a. On or before the 15th day of the preceding quarter – Quarterly reports of monitored, inspected and sanctioned hospitals; updated list of hospitals.
 - b. On or before January 31 – Annual complete listing of hospitals and other health facilities within their jurisdiction. *add*

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VI. ROLES AND RESPONSIBILITIES

1. HFSRB

- a. To set standards for the regulation of hospitals and other health facilities.
- b. To create/modify inspection and monitoring tools from time to time.
- c. To disseminate regulatory policies, standards and updated forms for information and guidelines to the DOH CHD-RLEDs.
- d. To provide consultation and technical assistance to regulatory officers from the DOH CHD-RLEDs and stakeholders in the regulation of hospitals and other health facilities.
- e. To conduct unannounced monitoring visits to hospitals and other health facilities to check for continuous compliance to the standards and requirements, as part of the oversight and monitoring functions.
- f. To monitor and evaluate annually the DOH CHD-RLEDs' performance in the regulation of hospitals and other delegated health facilities and services.
- g. To assess the readiness of the DOH CHD-RLEDs prior to full transition based on the monitoring tool.

2. DOH Field Implementation and Coordination Team / DOH CHD

- a. To ensure harmonized and standardized implementation of the regulatory policies nationwide.
- b. To ensure the provision of the much needed additional funding and manpower to the DOH CHD-RLEDs.
- c. To provide the necessary logistics to support the DOH CHD-RLEDs in the implementation of the Universal Health Care Act and this AO.

3. DOH CHD-RLED

- a. To commit to implement and uphold the standards and requirements set forth in the Assessment Tool for Licensing a Hospital, their ancillary and/or add-on facilities and services and other relevant policies issued by HFSRB.
- b. To provide feedback quarterly to HFSRB on the implementation of the AO.
- c. To ensure timely submission of accurate and relevant statistical data on hospitals and other delegated health facilities and services, as required or as needed.

4. Hospitals

- a. To continuously comply with the set forth standards and requirements in the Assessment Tool for Licensing a Hospital, and other relevant issuances.
- b. To provide feedback or evidence-based recommendations for future revision of the regulatory policy on licensing of hospitals.

VII. TRANSITORY PROVISIONS

1. The implementation of the provisions of this AO shall be in phases, with phase 1 commencing on **January 1, 2021**.
2. A self-evaluation shall be carried out by the DOH CHD-RLED on September 1, 2021, prior to the start of Phase 2 implementation to determine the readiness of the DOH CHD-RLED. Criteria for readiness shall include, but not limited to, adequate and qualified personnel hired, completion and satisfactorily passing the capacity building training (refer to Annex B – Evaluation Tool to Assess the Readiness for the Decentralization of Regulation of Levels 2, 3 General Hospitals and Specialty Hospitals, and its Ancillary Services).

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3. For Phase 1 (refer to Annex C):

a. DOH CHD-RLEDs shall:

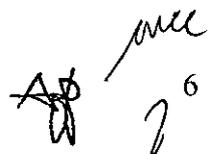
- i. In response to COVID-19
 - a) Implement the bed capacity allocation for COVID-19 patients in all levels of hospitals pursuant to Department Circular (DC) 2020-0406 titled Enforcement of Bed Capacity Allocation of Hospitals Dedicated for COVID-19 response, September 12, 2020, and in compliance to RA 11494 known as the Bayanihan To Recover as One Act.
 - b) Monitor for compliance all COVID-19 testing laboratories, whether hospital-based or non-hospital based, to the current price range for plate-based Reverse Transcription Polymerase Chain Reaction (RT-PCR), based on DC 2021-0016 titled Monitoring of Compliance to the Implementation of the Mandated Price Range for Reverse Transcription Polymerase Reaction in all COVID-19 Testing Laboratories, January 18, 2021, its future amendments, and other issuances setting the price range for other diagnostic platforms for COVID-19 testing, such as but not limited to cartridge-based RT-PCR and saliva specimen.
 - c) Renew DOH-LTO of non-hospital based COVID-19 testing laboratories.
 - d) Perform other assigned regulatory functions such as the interim certification of vaccination sites for COVID-19 vaccine roll-out.
 - ii. All complaints against hospitals regardless of level and specialty hospitals shall be handled and resolved by their respective DOH CHD, pursuant to Department Memorandum (DM) No. 2017-0324 titled "Delegation of Authority to Handle Specific Complaints to the Regional Office – Regulation, Licensing and Enforcement Division" dated July 24, 2017, and reiterated by DC No. 2020-0188 titled "Reiteration of DM No. 2017-0324, dated July 24, 2017 entitled "Delegation of Authority to Handle Specific Complaints to the Regional Office – Regulation, Licensing and Enforcement Division"" dated April 20, 2020.
 - iii. The DOH CHD-RLED shall create a Regional Health Facility Oversight Board (HFOB) Secretariat and shall directly coordinate with the Office of the Assistant Secretary of the Health Regulation Team (HRT-A) regarding complaints pertaining to Republic Act No. 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," signed August 3, 2017, its Implementing Rules and Regulations under AO 2018-0012 and its latest guidelines. The functions of the HFOB secretariat shall be as provided in Section II. B of the Department Personnel Order No. 2019-2430 titled "Reconstitution of the Health Facilities Oversight Board in Compliance to Republic Act (R.A.) 10932" dated March 1, 2019.
- b. HFSRB:
- i. Issuance of DOH-PTC and DOH-LTO of Hospital Extension Facilities based on DM 2020-0541 Interim Guidelines in the Regulation of Hospital Extension Facilities for COVID-19 patients, November 3, 2020, shall still remain with HFSRB. Inspection/Monitoring may be endorsed to the DOH CHD-RLED.
 - ii. Initial issuance of DOH-LTO of COVID-19 testing laboratories, whether hospital-based or non-hospital based, shall be by the HFSRB.

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- iii. Applications for DOH-PTC and DOH-LTO for Levels 2, 3 general hospitals and specialty hospitals shall still be processed and evaluated by HFSRB, with the DOH CHD-RLED joining as part of their capacity building.
4. For Phase 2:
 - a. All renewal of DOH-LTO for Levels 2, 3 general hospitals and specialty hospitals shall be submitted, processed and issued by the DOH CHD-RLED effective **October 1, 2021**.
 - b. Applications for new DOH-PTC and initial DOH-LTO for Levels 2, 3 general hospitals and specialty hospitals shall be processed and evaluated by the DOH CHD-RLED.
 - c. Initial and Renewal of DOH-LTO of COVID-19 testing laboratories, whether hospital-based or non-hospital based, shall be by the DOH CHD-RLED except those in health facilities still under the jurisdiction of HFSRB such as MFOWS, and Ambulatory Surgical Clinics and Dialysis Clinics with Ancillary Services.
 5. The DOH CHD-RLED shall not be given tasks in conflict with regulation, such as certification of programs like newborn screening which is a requirement for licensing a health facility, and shall focus on the performance of their regulatory functions.
 6. For **2021**, the following transition timeline shall be followed:
 - a. HFSRB
 - i. January to March: preparation of modules/materials for capacity building by HFSRB, with assistance from the Health Human Resource Development Bureau (HHRDB) through the DOH Academy
 - ii. April to June: Capacity building of the DOH CHD-RLED by HFSRB on DOH-PTC and DOH-LTO for levels 2, 3 general hospitals and specialty hospitals.
 - iii. July to October: DOH-PTC evaluation and inspections/monitoring of HFSRB with DOH CHD-RLED of levels 2 and 3 general hospitals.
 - iv. Hiring of additional personnel for HFSRB shall be undertaken simultaneously with the abovementioned activities.
 - v. Future capacity building shall be turned over to the DOH Academy.
 - b. DOH CHD-RLED
 - i. Cooperate and be readily available for the capacity building activities scheduled by HFSRB.
 - ii. Ensure the hiring of additional personnel for the Division by constantly communicating their needs to the Regional Director.
 - iii. Conduct self-evaluation on readiness for full implementation of this AO.
 7. All specialized facilities yet to be regulated such as, but not limited to, in-vitro fertilization, cancer facilities, and sleep laboratories, even if located within the premises of the hospital, shall still remain in HFSRB's jurisdiction until such time that capacity building of all the DOH CHD-RLED has been conducted. The DOH-LTO of these specialized facilities shall be separate from the DOH-LTO of the hospital until then.

VIII. REPEALING CLAUSE

All issuances, rules, and regulations, or parts thereof, inconsistent with this Order are hereby repealed or modified accordingly.



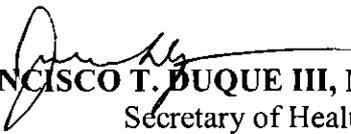
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IX. SEPARABILITY CLAUSE

In the event that any provision or part of this issuance is declared unconstitutional or rendered invalid by any court of law or competent authority, the portions not affected thereby shall remain in full force and effect.

X. 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.


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

List of relevant DOH issuances on Regulation of Levels 2, 3 general hospitals and specialty hospitals:

- a. For Certificate of Need: AO 2006-0004 titled "Guidelines for the Issuance of Certificate of Need to Establish a New Hospital," dated March 13, 2006, and its Amendments
- b. For DOH-PTC: AO 2016-0042, titled "Guidelines in the Application for Department of Health-Permit to Construct (DOH-PTC)," dated December, 14, 2016, and its Amendment
- c. For DOH-LTO: AO 2012-0012, titled "Rules and Regulations Governing the New Classification of Hospitals and other Health Facilities in the Philippines," dated July 18, 2012, and its Amendments and Assessment Tool: AO 2018-0016, titled " Revised Guidelines in the Implementation of the One-Stop Shop Licensing System," dated June 4, 2018
- d. For renewal of DOH-LTO: AO 2019-0004, titled "Guidelines on the Annual Cut-off Dates for Receipt of Complete Applications for Regulatory Authorizations Issued by the Department of Health," dated April 30, 2019
- e. For COVID-19 Testing: AO 2020-0014, titled "Guidelines in Securing a License to Operate a COVID-19 Testing Laboratory in the Philippines," dated April 7, 2020, and its Amendments

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EVALUATION TOOL

To Assess the Readiness for the Decentralization of the Regulation of Levels 2 and 3 General Hospitals, Specialty Hospitals and its Ancillary Services

OBJECTIVE: To determine the readiness of the Regulation, Licensing and Enforcement Division (RLEDs) of the Department of Health (DOH) - Centers for Health Development (CHDs) for decentralization of the regulation of Levels 2 and 3 General Hospitals, Specialty Hospitals and its Ancillary Services.

CHD-RLED: _____ **Date Accomplished:** _____
(indicate Region) *(month/day/year)*

Criterion 1 : ADEQUACY OF REGULATORY OFFICERS IN CHD-RLEDs						
PURPOSE	To determine adequacy of the personnel in CHD-RLEDs by determining the percentage of hired personnel based on the gaps on their current staffing as identified by the CHD-RLEDs.					
INSTRUCTION	<ol style="list-style-type: none"> Determine the additional regulatory officers needed* by your office for the decentralization of regulation of Levels 2 and 3 general hospitals and specialty hospitals and its ancillary services. * Identified gaps on current personnel based on the data submitted by the CHD-RLEDs on the item on the additional staff needed by the RLEDs for decentralization on the Survey on Operational Capacity of CHD-RLEDs. Determine the percentage of the newly-hired personnel (both Regular Item and Job Order Personnel) to the number of additional regulatory officers needed for the decentralization for every professional cadre. Assign the point/s acquired for each professional cadre based on the point scoring below. Fill-out the table below by putting (x) on the accumulated point/s for every professional cadre and compute for the total points acquired. Compute for the total score for Criterion 1 in accordance with the formula box stated below. 					
POINT SCORING	Condition					Equivalent Point/s
	0% or <u>NO</u> additional personnel are hired;					0
	1% to 25% of the identified gap in manpower are filled up by hiring additional personnel;					1
	26% to 50% of the identified gap in manpower are filled up by hiring additional personnel;					2
	51% to 75% of the identified gap in manpower are filled up by hiring additional personnel;					3
76% to 100% of the identified gap in manpower are filled up by hiring additional personnel.					4	
Professional Cadre						
	0	1	2	3	4	Points
1. Physician						
2. Nurse						
3. Engineer / Architect						
4. Medical Technologist						
To compute for the total score for Criterion 1:			Total Points Garnered			
$\text{Total Score} = \left[\left(\frac{\text{(total points garnered)}}{16} \right) \times 100\% \right] \times 0.6$			Total Score			

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Criterion 2: CAPACITY BUILDING OF REGULATORY OFFICERS IN CHD-RLEDs			
PURPOSE	To determine the percentage of personnel in CHD-RLEDs who completed the capacity building activities and successfully passed its corresponding evaluation test/s.		
INSTRUCTION	1. Determine the current percentage of the total personnel who completed the capacity building activities and successfully passed its corresponding evaluation test/s*, and fill out the table below. <i>* Only Personnel who completed the minimum number of hours of didactics on capacity building will be allowed to take the evaluation tests for regulatory officers. The overall passing grade for the evaluation tests is 80%.</i> 2. Compute for the total score for Criterion 2 in accordance with the formula box stated below.		
Total Number of Personnel	Total Number of Personnel who successfully passed the evaluation test	Percentage (%) $\% = \frac{\text{Number of Personnel who passed the evaluation test}}{\text{Total Number of Personnel}} \times 100\%$	
<i>To compute for the total score for Criterion 2:</i> Total Score = Percentage (in percent) x 0.4		Total Score:	
OVERALL SCORE			
Score on Criterion 1	Score on Criterion 2	Overall Score (out of 100%) (sum of scores in Criteria 1 and 2)	
REMARKS	CHD-RLEDs shall be considered ready for the decentralization of regulation of Levels 2 and 3 general hospitals and specialty hospitals and its ancillary services if they garnered an overall score of <u>80%</u> or above.		
Additional Information : NUMBER OF HIRED REGULATORY OFFICERS IN CHD-RLEDs			
INSTRUCTION	1. Fill out the table below by tabulating the number of all the newly-hired regulatory officers.		
Regulatory Officers hired <i>(indicate profession)</i>	Number of Personnel hired		
	Regular Position	Job Order / COS	Total
1. Physician			
2. Nurse			
3. Engineer			
4. Architect			
5. Medical Technologist			
Other Licensing Officer/s <i>(indicate profession)</i>			
1.			
2.			
3.			
4.			
5.			
6.			
7.			
Total Number of hired personnel			
Prepared by:		Verified by:	
Name:		Name:	
Position/Designation:		Position/Designation:	
Date:		Date:	

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PHASE 1	HFSRB	DOH CHD-RLED
A. COVID-19 responses		
a. Bed Capacity Allocation of Hospitals Dedicated for COVID-19 response		For all levels of hospitals
b. Monitoring of Compliance to the Mandated Price Range for plate based RT -PCR		For both hospital-based and non-hospital based COVID-19 Testing Laboratories
c. Regulation of Hospital Extension Facilities for COVID-19 patients	DOH-PTC and DOH-LTO	Joining as part of capacity building
d. COVID-19 Testing Laboratories	Initial LTO whether hospital based or non-hospital based	Renewal of non-hospital based COVID 19 testing laboratory
B. Regulation of Levels 2,3 general hospitals and specialty hospitals	DOH-PTC and DOH-LTO	Joining in as part of their capacity building
C. Handling of Complaints		Resolution of all complaints against hospitals
D. Creation of Health Facility Oversight Board Secretariat		Coordinate with the Office of the Assistant Secretary of the Health Regulation Team regarding complaints on anti-hospital deposits

PHASE 2	HFSRB	DOH CHD-RLED
A. Regulation of Levels 2,3 general hospitals and specialty hospitals		All renewal of DOH-LTO Applications for new DOH-PTC and initial DOH-LTO
B. COVID-19 Testing Laboratories	Non-hospital based still under the jurisdiction of HFSRB such as MFOWS, and Ambulatory Surgical Clinics and Dialysis Clinics with Ancillary Services.	Initial and Renewal of DOH-LTO, whether hospital-based or non-hospital based

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