

## What is the Current Situation of Regulation of Hospitals, Health Facilities, and Health Services in the Philippines?

Based on the Situational Analysis of the Philippine Regulatory Landscape and the Appropriate Enabling Environment towards the Operationalization of the Reform on Hospitals, Health Facilities and Health Services by Dr. Katherine Ann V. Reyes

### BACKGROUND

#### Current Regulatory Regime

#### HOSPITALS

- Republic Act 4226, or the Hospital Licensure Act of 1965, mandates the regulation of hospitals. Prescriptive standards cover key elements of hospital operations, such as safety and quality, and are formulated by the DOH - Health Facilities and Services Regulatory Bureau (HFSRB), key experts, and the FDA. Hospital licensing is done according to service level capacity and standard compliance.
- Issuance of Certificates of Need (CON) is intended to rationalize establishment of hospitals and ensure equitable access to health services.

#### HEALTH FACILITIES

- HFSRB currently regulates 16 types of health facilities, and different laws and administrative issuances govern health facility regulation. An umbrella policy that provides a universal framework of cohesion across the different health facility policies is still needed.
- Prescriptive standards for each type of health facilities were crafted together with relevant stakeholder/s. DOH as the regulating authority provides assistance to health facilities to support their compliance to policies.
- The “All-or-None” approach is used in evaluating hospitals and health facilities for alignment to standards. Hospitals face downgrading to lower classifications or are subject to non-issuance of licenses if they are non-compliant.

#### HEALTH SERVICES

- Health services regulation is fairly recent and the development of standards is similar to health facilities.
- The regulatory role is shared by DOH-HFSRB and DOH-Regulations, Licensing and Enforcement Division (RLED) however recent policies on the operationalization of ambulances was developed by DOH-Health Emergency Management Bureau (HEMB), private providers, specialty societies, the Department of Interior and Local Government, Land Transportation Office and the Philippine Charity Sweepstakes Office.

### CURRENT ISSUES TO BE ADDRESSED

- **The current regulatory framework of hospitals, health facilities, and health services needs to keep up with the rapidly changing landscape of health service delivery.**
  - The Hospital Licensure Act is outdated, there is still no umbrella legislation to cover for other types of health facilities. Mandates and updates are issued through DOH administrative orders which have limited scope and lack the power of law.
  - The principles, criteria, and usability of CON needs to be reviewed to balance the goals of the government, hospitals and patients.
- **A systematic approach is needed on how to respond to the quickly-innovating regulated sectors, and strong political influences on regulatory activities further complicates this.**
  - Lack of robust evidence makes it a challenge to determine the right mix of incentives or disincentives that will provide the best result in attaining system efficiency. It also poses a challenge in determining the impact of regulatory tools on outcomes.
  - Licensing is currently the main tool for regulation. It is protective but maybe limited relative to the expanding and evolving activities within hospitals and health facilities.

## RECOMMENDATIONS

### Update regulatory framework for hospitals, health facilities, and health services

- Adequately protect and support DOH's role to regulate and delineate roles and responsibilities of offices
- Expand and update regulatory mandates to be more cohesive, including adopting a framework of cohesion across health facilities
- Ensure attainment of objectives through stringent application and revision of prescriptive standards
- Determine options for improving engagement with regulated sectors

### Institute an evidence-informed mechanism towards a more responsive regulatory landscape

- Provide a platform for regulators to communicate and consolidate technical and political discourse on hospital and health facility regulation
- Document and highlight the importance of regulation in the attainment of health sector goals
- Increase public awareness and participation on regulation and aspire to include fairness in cost and equity of access to future deliverables of health regulation

## ANNEX

### Key policies governing health facilities activities:

- ✓ DOH AO 2012-0012 Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines
- ✓ Republic Act 9165 Comprehensive Dangerous Drugs Act
- ✓ Republic Act 9288 Newborn Screening Act
- ✓ Republic Act 7719 National Blood Services Act
- ✓ Department Circular No 2018 – 0039 Revised Assessment Tools for Licensing Blood Services Facilities
- ✓ Republic Act 4688 Clinical Laboratory Law
- ✓ Department Circular No 2018-0049 Non-Participation of a Clinical Laboratory in the External Quality Assessment Program (EQAP) of the National Reference Laboratories
- ✓ Department Circular No 2018-0130 Clarification on the Guidelines on Referral or Outsourcing of Clinical Laboratory Services
- ✓ Presidential Decree 1542 Providing for the Regulation and Licensing of Dental Prosthetic Laboratories

### Key policies governing hospital activities:

- ✓ Republic Act 4226 Hospital Licensure Act
- ✓ DOH AO 2012-0012 Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines
- ✓ DOH AO 2018-0012 Implementing Rules and Regulations of Anti-hospital Deposit Law
- ✓ DOH Department Circular 2018-0131 Revised Licensing Assessment Tool for Hospitals
- ✓ DOH AO 2018-0016 One-stop shop online licensing system

### Key policies governing health facilities:

- ✓ AO 2010-0003 National Policy on Ambulance Use and Services
- ✓ AO 2016-0029 - Rules and Regulations Governing the Licensure of Ambulances and Ambulance Service Providers
- ✓ AO 2018-0001 Revised Rules and Regulations Governing the Licensure of Land Ambulances and Ambulance Service Providers

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