RATIONALIZING REGULATION OF HEALTH FACILITIES THROUGH A RISK-BASED APPROACH

BACKGROUND

The Universal Health Care Act or Republic Act No. 11223 states that, *"The DOH shall institute a licensing and regulatory system for stand-alone health facilities, including those providing ambulatory and primary care services, and other modes of health service provision."*

Currently, the Department of Health (DOH), through the Health Facilities and Services Regulatory Bureau (HFSRB) and Center for Health Development Regulation Licensing and Enforcement Divisions (CHD-RLEDs), already regulates facilities providing ambulatory and primary care services such as Birthing Homes, Infirmaries, OFW Clinics, Ambulatory Surgical Clinics, and Dialysis Clinics.

However, there are still other types of primary care facilities existing in the country that are not yet being regulated by the Department, such as Medical Outpatient Clinics that include both private and public medical clinics (ex. Rural Health Units, Health Centers, and Barangay Health Stations) and Dental Clinics (except those in occupational establishments and private schools).

CHALLENGES IN EXPANDING THE SCOPE OF REGULATION

- **Inadequate Manpower to License a Large Number of Health Facilities**

  DOH presently regulates nineteen (19) types of health facilities and services offering different levels of care. Among the 19, HFSRB regulates twelve (12) types while CHD-RLEDs regulate ten (10) types as shown in Table 1 below.

TABLE 1. SCOPE OF REGULATION OF HFSRB AND CHD-RLEDS

HFSRB	CHD RLEDs
1. Levels 2 & 3 General Hospital and Specialty Hospitals 2. Ambulance Service (Levels 2 and 3 Hospital and Non-institution-based) 3. Ambulatory Surgical Clinic 4. Dialysis Clinic 5. Drug Abuse Treatment and Rehabilitation Center 6. Stem Cell Facility 7. Medical Facility for Overseas Workers and Seafarers 8. Newborn Screening Center 9. Drug Testing Laboratory 10. Kidney Transplant Unit 11. HIV Testing Laboratory 12. Blood Service Facility (Blood Center)	1. Level 1 General Hospital 2. Ambulance Service (Level 1 Hospital) 3. Clinical Laboratory 4. Dental Laboratory 5. Infirmary 6. Birthing Home 7. Laboratory for Drinking Water Analysis 8. Psychiatric Care Facility 9. Blood Service Facility (Blood Collection Unit) 10. Dental Clinic (for Occupational Establishments and Private Schools only)

In 2017, it was estimated that there are about 9,964 regulated health facilities nationwide, which greatly outnumbers the 270 regulatory officers from HFSRB and CHD-RLEDs (Table 2).

TABLE 2. HUMAN RESOURCE CAPACITY OF HFSRB AND CHD-RLEDS, JANUARY 2018

DOH	No. of Regulated Health Facilities	No. of Regulatory Offices
All CHD-RLEDs	7,660	226
HFSRB	2,304	44
Total	9,964	270

Source: HFSRB, 2018

With the directive to expand the regulatory scope especially to other primary care facilities such Rural Health Units (2,500[1]) and Barangay Health Stations (42,045[2]) among others, the DOH needs to explore strategies that will enable its regulatory arm to fulfil its role at a pace that matches the rate of expansion and considers the limited resources.

- **Unclear Delineation of Roles and Responsibilities of RLEDs**

  Unlike the Food and Drug Administration and the Bureau of Quarantine which have field offices directly under their supervision, the RLEDs are directly under the management of CHD Directors.

  HFSRB only exercises an oversight function over RLEDs. This has implications in the harmonization of implementation of licensing standards. Moreover, RLEDs are also tapped to perform non-regulatory functions as directed by their respective CHD Directors, such as health program implementation and monitoring and involvement in CHD procurement activities. This effectively reduces the time allocated exclusively for the performance of their regulatory functions.

- **Limited Enforcement and Lack of Quasi-judicial Powers of HFSRB**

  The regulatory authority of HFSRB over health facilities is limited in terms of its scope and capacity to enforce sanctions due to its lack of quasi-judicial powers. The legal mandate of HFSRB to regulate hospitals is based on Republic Act No. 4226, also known as the Hospital Licensure Act, which has not been reviewed and revised since 1965.

[1] 2018 Data from the DOH National Health Facility Registry
[2] 2018 PSGC, Philippine Statistics Authority (Assuming 1 barangay has 1 BHS)

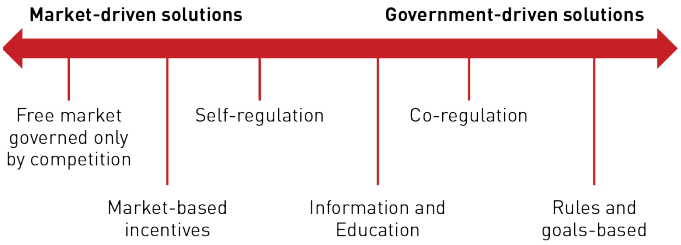
A STRATEGY AND SOLUTION: RISK-BASED APPROACH

Shifting from 'Command and Control' to 'Smart' Regulation

The functioning regulatory framework by which DOH regulates health facilities (Table 1) in the country is solely through the 'command and control' approach. This approach requires health facilities to secure authority from the DOH before they can operate in the market. The processes by which authorizations are issued involve a myriad of requirements and steps depending on the type of health facility. Facilities must pass through a uniform route in complying with sets of standards to be granted a Permit to Construct and License to Operate or Certificate of Accreditation, among others. Subjecting all types of health facilities to this type of regulation has been challenging for both government and health facility owners.

Furthermore, implementing command and control comes with high administrative costs for the DOH, which is also costly for health facility owners. These owners bear the burden of opportunity costs with every regulatory requirement or standard the government imposes.

With the quickly-changing landscape of health facilities - increasing number of regulated health facility types, other types of existing health facilities in the pipeline for regulation, and emerging health facilities - vis-a-vis limited resources, the DOH needs to transition from command and control to 'smart' regulation. In smart regulation, regulatory intervention is selective and a combination of appropriate regulatory alternatives are utilized. (Figure 1).



Source: National Audit Office

FIGURE 1. SPECTRUM OF REGULATORY ALTERNATIVES

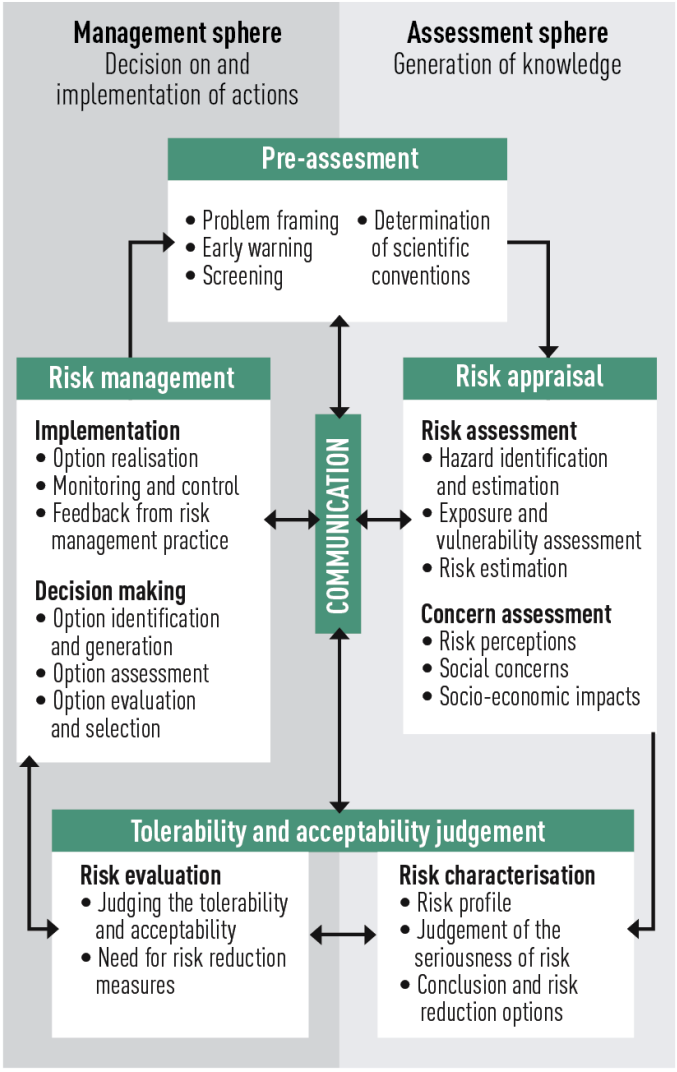
Ensuring Safety and Quality of Health Services through Risk-Based Approach in Regulation

Different types of health facilities pose different degrees of risks to the public - not all risks are equally important. Failure to set risk priorities and over-regulation of risks may result in wastage of resources due to disproportionate intervention of government in markets to the scale of risks (OECD, 2010). DOH must then be able to identify, appraise, and manage risks of services in health facilities. This risk-based approach in regulation can help DOH effectively and efficiently attain its regulatory goals in alignment with UHC. This also has the potential to reduce costs both for regulation and business.

Objectives in shifting to risk-based regulation are:

1. To improve regulatory efficiency by allocating resources where risk is greater;
2. To improve and rationalize regulatory policy-making process; and
3. To facilitate ease of doing business for health facility owners by reducing unnecessary bureaucracy.

DOH through HFSRB can adopt an analytical risk policy framework to assess, manage and review risks of different types of health facilities (Figure 2).



Source: Renn and Graham (2006)

FIGURE 2. THE INTERNATIONAL RISK GOVERNANCE COUNCIL RISK GOVERNANCE FRAMEWORK (RENN AND GRAHAM, 2006)

Based on the risk assessment, the appropriate regulatory instrument or a combination of regulatory or non-regulatory approaches can be utilized for each type of health facility. This means that health facilities with higher risks would be regulated strictly and closely than others that have lower or no risks. HFSRB would then be able to allocate its resources based on a risk management approach appropriate for each health facility.

CONCLUSION

The increasing demand for HFSRB to regulate all types of health facilities, including primary care facilities, poses a great challenge for HFSRB with its limited resources and legislative regulatory capacity. It must adopt a Risk-Based approach in setting priorities in which health facilities to regulate and how to regulate them, based on risk assessments and management. The regulatory instrument that shall be applied to a particular type of health facility shall be based on its level of risk.

This approach provides a more rational system for protecting patients from potential risks of health services without depriving health facilities the opportunities to innovate. This shall improve the efficiency of government by achieving its regulatory goals with minimal regulatory costs.

RECOMMENDATIONS

1. **Reform the regulatory framework of HFSRB by shifting to risk-based regulation**

   - Reforming the regulatory framework of HFSRB by shifting to risk-based regulation requires necessary complements in its legislative mandate. Adopting a new regulatory approach cannot be carried out through piecemeal initiatives and isolated efforts of HFSRB. It needs a coherent, whole-of-government approach to create the desired regulatory environment.

   - It is critical that the legal mandate of HFSRB to regulate all types of health facilities be strengthened and its scope expanded. This mandate must also expand the enforcement power of HFSRB and CHD RLEDs by having line agencies at the regional level which thereby shall facilitate the harmonization in the implementation of licensing standards.

   - HFSRB must also be given quasi-judicial powers to effectively enforce regulatory actions on health facilities that endanger patient safety. Due to the increasing regulatory scope of HFSRB, it is vital that it has the sufficient resources to upgrade its services and facilities, human resource development, and logistics.

2. **Capacitate HFSRB regulatory staff in conducting analytical risk assessments and management**

   In the development of risk based-regulatory policies, the technical staff of HFSRB must be capacitated in conducting analytical risk assessments and management. Regulatory Impact Analysis (RIA) must be integrated and institutionalized in the policy process of DOH. All regulatory policies, as well as risk assessments, must undergo RIA to ensure regulatory quality. This provides evidence-based data for better decision making.

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The **NHSM BRIEF** is a background document for discussion during the 3rd National Health Sector Meeting prepared by the Health Policy Development and Planning Bureau in collaboration with the Health Regulation Team.

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