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>
<thead>
<tr>
<th>DOH</th>
<th>No. of Regulated Health Facilities</th>
<th>No. of Regulatory Offices</th>
</tr>
</thead>
<tbody>
<tr>
<td>All CHD-RLEDs</td>
<td>7,660</td>
<td>226</td>
</tr>
<tr>
<td>HFSRB</td>
<td>2,304</td>
<td>44</td>
</tr>
<tr>
<td>Total</td>
<td>9,964</td>
<td>270</td>
</tr>
</tbody>
</table>

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.
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-à-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).

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).

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. 

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.

REFERENCES


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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