Regulatory Reforms

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Predicaments of the Philippine Regulatory System

Regulation plays a vital role in the success of Universal Health Care by ensuring that the people, especially the poor will have access to quality and accessible health products, devices, facilities and services. Health care regulatory system is an important imperative of the government to ensure access to quality and accessible health products, devices, facilities and services, especially those commonly used by the poor through the set of standards and enforcements. With the adoption of Universal Health Care, the government should be able to assert its regulatory authority to ensure accessibility of quality healthcare services. Its regulatory bodies should have adequate resources. However, this has been a serious challenge for the government. The mechanisms for regulation of health goods, services and facilities remain inadequate, weak and unresponsive.

Regulatory system aims to provide a set of methods to influence behavior. This particular reform agenda is part of the six building blocks for building stronger health systems[1] and contributes to the overall understanding, application and adoption of a true Philippine Universal Health Care.

The roles of regulation are fairly established,[2] these are:

- Establishing Rules Governing the Private Sector
- Protecting Buyers from Their Own Inability to Judge Quality
- Counteracting "Supplier Induced Demand"
- Improving Access
- Advancing Specific Moral Principles
- Counteract Monopoly
- Counteract Externalities

Health regulatory authority, in general, grapples with scarce resources, inadequate staff and capability, inefficient use of available technology, and lack of progressive technological development. "There are no funds for technical and operations researches, which are necessary to provide the basis for standards development. There are not enough training facilities, testing laboratories and experts to handle the qualification requirements for regulation of manpower, certification/conformity testing and monitoring of regulated products."[3]

Another identified factor includes the lack of quasi-judicial power amongst regulatory authorities as they are currently "limited to standards development, inspection, licensing and accreditation, assessment, monitoring and imposition of fees."[3]

Regulation of Health Facilities

The Bureau of Health Facilities and Services (BHFS) of the DOH is in charge of the regulation and licensure of health facilities and services such as hospitals, clinics, laboratories and other health service establishments. In support of the BHFS is Philhealth accreditation which provides incentive for compliance in the quality guidelines.

However, the criteria used in BHFS licensure and DOH accreditation are mostly based on inputs like number of beds and the presence or absence of certain medical equipments and medical professionals. Outputs and performance indicators like in-patient and out-patient visits, and the health condition of the discharged patient are not given enough weight."[4]

Despite the presence of various laws and guidelines on quality assurance and efficient investment, health facility remains substandard and fragmented. These laws and guidelines include: Administrative Order 21 s. 2007 Harmonization and Streamlining of Licensure System for Hospitals; Guidelines for the issuance of certificate of need to establish a new hospital (AO 29 and its amendments AO-4, AO-4A and AO-4B); the Rationalization Plan of health facilities; RA 4226 (An Act Requiring the Licensure of all hospitals in the Philippines and Authorizing the Bureau of Medical Services to Serve as the Licensing Agency); and other guidelines concerning birthing facilities, private clinics, blood banks, dialysis center, etc.

The problem lies in the enforcement of the laws and authority. In 1999, the Department of Health identified that the lack of manpower, technical, organizational and legal constraints hamper the enforcements of the policies and regulations.[5] They cited that the competency and skills of regulatory officers are inadequate. Sotto (2006) also noted that:

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> *"Until recently, there was not even an introductory training course for regulatory officers of the DOH. In the past, regulatory officers attended a two-week training course conducted by the UP College of Public Health. A few were sent abroad to gain exposure in standards setting and enforcement practices of other countries. Except for the Bureau of Health Devices and Technology, which requires its regulatory officers to take a Master of Science in Applied Physics, Major in Medical Physics, an advanced degree is not compulsory for the regulatory officers below division chief level."*[6]

The lack of technical capacity has been compounded by the inadequate number of staff. "With more than 1,700 registered hospitals in the Philippines alone, a total manpower complement of approximately one hundred staff from the BHFS and CHD is generally unsatisfactory to provide regular and quality assessment and monitoring of these hospitals and health facilities."[6]

As a result, some of the health facilities, particularly those maintained by local government units such as rural health centers and barangay health stations, are substandard and dilapidated, if not, none existent. Health facilities are uncoordinated and fragmented. In many cases, primary and secondary hospitals are situated next to rural health units, but were largely performing the same basic outpatient health center functions.[7] Contrary, there are localities without healthcare providers particularly in the far-flung areas. Close to 60% of all accredited hospitals are located in Luzon while over 70% of free standing dialysis clinics are found in the National Capital Region alone. Moreover, there are hospitals that have deteriorated thus, can no longer perform the services according to their level. More often than not, such cases were neglected for lack of adequate resources to respond to the resource needs.

The health referral system lost cohesion post-devolution. Logistics, transport, patient referral protocol, distinctions (complementarities) between levels of service were all affected adversely by lack of clarity regarding local government co-operation and under-financing of the operational costs of the district hospital.[7]

Regulation of Health Professionals

The Professional Regulation Commission (PRC) administers, implements and enforces the regulatory policies for the practice of health-related professions. It administers licensure exams, enhancement and enforcement of professional, occupational, ethical and technical standards.

In support of the PRC are the Specialty Societies that practice self-regulation in their respective field of professions. These societies monitor the practice and hold continuing education programs for their members and compel members to participate in conferences, symposia and other society activities. Societies also police unethical behavior and those found guilty of unethical conduct are expelled from its roster and subjected to further disciplinary actions by the Philippine Medical Association which is the umbrella organization of all medical societies.

Philhealth also contribute to the enforcement of standard for healthcare providers through accreditation. Accredited providers may participate in the National Health Insurance Program which ensures quality of service. Accreditation may be revoked or suspended when acts are committed resulting in adverse patient outcomes or when there is evidence of fraudulent claims.

Despite various regulatory mechanisms, gaps have been identified which affect access to quality health service amongst providers. The Philippine Health Human Resource (HRH) Master Plan identified the lack of an integrated HRH system or an overarching framework that will ensure efficient production, deployment, regulation, entry and exit.

Other issues identified include the standard workforce to population ratio, workforce to bed ratio; and the maldistribution of health professionals concentrating primarily in the urban areas.

Based on the HRH Master Plan, the workforce to population and bed ratio, stipulated in the DOH A.O. 147 s. 2004, is insufficient to respond to meet the patients' needs. Moreover, there were necessary positions that were not included in the minimum standard. For the case of the Rural Health Units, DOH A.O. 100 s. 2000 stipulates the standard workforce to population ratio; however, it is also limited to doctors, nurses, midwives and rural sanitary inspectors and fails to take into account medical technologists, dentists and other health professionals which counter the Sentrong Sigla Quality Standards.

The low standard is compounded by maldistribution of health workforce between rural and urban areas. It has been reported that 50 to 70 percent of all medical practitioners are concentrated in the cities (Department of Health, 1994). Moreover, it was recorded in 2005 that 36 percent of the 7,671 government doctors are in the National Capital Region while the other regions average 300 doctors. However, the ARMM and the CARAGA, two of the poorest rural regions only have 89 and 76, respectively.[8] In the case of Philhealth accreditation, 35% of its accredited doctors are based in NCR. This is about eight times more than the average number of Philhealth accredited doctors in regions outside NCR.

Regulation of Health Devices

The Bureau of Health Devices and Technology (BHDT), created by P.D. 480 and P.D. 1372, responsible for formulating and implementing standards for radiation facilities and devices used in medicine, dentistry, veterinary medicine, industry, education, research, anti-crime, military and consumer applications. It also conducts health technology assessment, studies and researches on radiation

devices and technology and provides technical assistance and consultative services to stakeholders.

However, due to meager resources and limited technological capacity, BHDT lags behind the industry. It has not been able to cope with the technological progress as the industry invests heavily in research and development to produce more products to be imported to the country.

Technical and operations training remains a challenge as there are very few experts to handle the regulation of quality standards for healthcare, certification/conformity testing and monitoring of regulated products. There are difficulties in dealing with industry as health regulators may not possess the skills to substantially manage resources or industry people.

Maldistribution is also a problem for medical devices. Of the 3,860 basic X-ray facilities, 1,200 can be found in the National Capital Region. Of the total of 5,141 facilities are found in the country, across the regions. Regions with least categories are CAR, ARMMM and CARAGA. General Radiography facilities found in CAR, ARMM and CARAGA are 67, 23 and 46, respectively.[9]

Regulation of Medicines

RA 9711 reorganized and expanded the existing setup of the Bureau of Food And Drugs (BFAD) into Food and Drugs Administration (FDA) with four specialty areas that include: (1) Center for Drug Regulation and Research (to include veterinary medicine, vaccines and biologicals); (2) Center for Food Regulation and Research; (3) Center for Cosmetics Regulation and Research (to include household hazardous/urban substances); (4) Center for Device Regulation, Radiation Health, and Research, formerly the Bureau of Health Devices and Technology become fully integrated with the FDA.

Prior to the law, BFAD had to operate with meager resources, inadequate staff, lack of technological development in carrying out its responsibility of regulating drug industry and their products, devices, vaccines, food, cosmetics, nutriceuticals and hazardous household chemicals and toys.

The BFAD, aware of such shortcomings, has conducted studies that show that there is a grave lack of manpower where regulated establishments and products overwhelm inspectors such in the tables shown below. The ratio of the number of Food and Drug Regulation Officers (FDROs) with the number of establishments is 1:202; while the ratio of the number of evaluators for the PSD with the number of products is 1:1,513. These data somewhat give an overview of how BFAD is in urgent need for reorganization and systems reform.

In addition to overseeing the safety of food and cosmetics, the agency also faces a formidable load of nearly 20,000 registered drug products. The equipment for chemistry, manufacturing and controls for registration approval need to be upgraded to cope with an increasing number of applications for product registration numbering to approximately 150 to 200 applications monthly.[10]

Aside from the regulatory mechanisms, accepted standards in manufacturing such as the Good Manufacturing Practice (cGMP) have not been satisfactorily and fully implemented. As of October 4, 2010, there are only 57 establishments with cGMP. The implementation of full compliance to GMP has been repeatedly postponed. The prevailing argument of most drug companies is that they need to continue operating in order to have profits to plough back into investments for their plant's GMP. cGMP certification must also be applied to the source of finished medicine products imported by local importers.[10]

CHD	No. of Establishments	FDROs	Ratio
I	2656	6	1:443
II	1649	6	1:275
III	4149	11	1:377
IV A&B	6520	12	1:543
V	1840	10	1:184
VI	2248	10	1:225
VII	3924	10	1:392
VIII	1630	8	1:204
IX	1890	10	1:189
X	1536	9	1:171
XI	3229	8	1:404
XII	1778	7	1:254
CAR	741	4	1:185
ARMM	31	3	1:10
CARAGA	609	6	1:101
NCR	9894	100	1:96
TOTAL	44,333	220	1:202

Table 1. Establishments vs. CHD Manpower Complement per CHD (2006)

There are also issues in poor regulation of generic drugs in terms of the capacity to comply with bioequivalence requirement for establishing product interchangeability as stipulated by the Generics Law of 1998 and further by the Universally Accessible Cheaper and Quality Medicines Act of 2008.

Another significant omission of the agency as a truly effective regulatory agency is the absence of a functional adverse drug reactions (ADR) monitoring and pharmacovigilance system. In 1995, the Philippines became a full member of the World Health Organization Adverse Drug Reaction Surveillance System based in Uppsala, Sweden (now the WHO-Uppsala Monitoring System) through the establishment and early accomplishments of the National Adverse Drug Reaction Committee (NADRAC). However, over time, the Philippines acquired almost a non-functional status in the WHO program. Currently, FDA has embarked on an effort to revive ADR monitoring, spearheaded by its new ADR Unit which organizes training seminars all over the country for key DOH-retained and LGU-operated hospitals and pharmacies, but not the private health sector yet.

FDA also failed to regulate unethical intensive marketing practices which led to "asymmetry of information" where the consumers know very little about the nature of the product and the variety of choices and options, while the drug manufacturers and intermediaries particularly the physicians and pharmacists know much more. The asymmetry of information led to brand loyalty amongst consumers and physician resulting to some sort of monopoly which allows firms to set prices above the competitive level. This has also resulted to irrational drug use.

FDA failure in regulating marketing practices of drug industry has led to some form of industry group self-policing their members to undertake ethical marketing,

Establishment Type	Number
MANUFACTURERS:	12,489
DRUG	246
COSMETIC	176
MEDICAL DEVICE	40
HOUSEHOLD HAZARDOUS	227
FOOD	11,800
TRADERS:	602
DRUG	391
COSMETIC	190
MEDICAL DEVICE	21
DISTRIBUTORS:	7,341
DRUG	3,450
COSMETIC	505
MEDICAL DEVICE	893
HOUSEHOLD HAZARDOUS	222
FOOD	2,271
RETAIL OUTLETS:	23,901
TOTAL	**44,333**

Table 2. Breakdown of BFAD Regulated Establishments (2006)

PRODUCT	NUMBER
DRUGS (Pharmaceutical)	11,135
COSMETICS	9,579
FOOD	20,930
MEDICAL DEVICE	2,137
HOUSEHOLD REMEDY	379
MEDICAL OXYGEN	29
PITC Products	181
DONATION	1,850
VETERINARY	392
HERBAL MEDICINES	18
VACCINES	216
REAGENTS (Diagnostic)	177
Household Hazardous	1,393
TOTAL	**48,416**
NO. OF EVALUATORS IN PSD = 32	**RATIO: 1:1,513**

Table 3. BFAD Registered Products vs. number of evaluators (2006)

advertising and promotions through a code. This industry code, while not perfect, defines the limits of permissible interaction and relationship between prescribers and drug industry. But since this code covers only the research and development based industry, it does not cover local drug companies or non-members of the Pharmaceutical Health Care Association of the Philippines (PHAP).

The poor compliance to regulatory bodies and accepted standards undermines the quality, safety and efficacy of the pharmaceutical product. Moreover, the market imperfections and inability of the government to address the issues through competitive market mechanisms perpetuates the proliferation of high cost of medicines. The pharmaceutical market remains afflicted by substandard, counterfeit drugs that threaten the life of the consumers.

Regulation of Health Financing

In 1994, the DOH issued the Rules and Regulations on the Supervision of Health Maintenance Organizations (AO No. 34 s. 1994), which gave the Office for Health Facilities Standards and Regulations (OHFSR) authority to exercise regulatory functions for HMOs, whether investor-based, community-based or cooperative-based.[11] The OHFSR issues licenses and permits, including the Clearance to Operate, to HMOs, and provides medical and employer organizations with a list of HMOs whose clearance has been issued, suspended, cancelled or revoked.

Despite the mandate, HMO operation in the country has been generally regarded as highly unregulated. The framework for regulation remains to be the Presidential Decree No. 612 (Insurance Code) issued in 1974 and amended by Presidential Decree No. 1460 (also known as the Insurance Code of 1978).

Based on the DOH A.O., the minimum facilities for an investor-based HMO acting as a stock corporation are the management of one tertiary hospital or affiliation with five tertiary hospitals, and an outpatient clinic with basic diagnostic facilities for resting ECG, chest and extremity X-rays and CBC, urinalysis and fecalysis. Meanwhile, community-based or cooperative HMOs operating as non-stock or non-profit are required to be affiliated with one general hospital and one outpatient clinic. As of December 31, 2005, there are seventeen (17) DOH-licensed HMOs in the country.

Despite the mandate from the DOH and Insurance Commission, there remains some regulatory ambiguity. "Pre-need and health care plans that are considered as "insurance" products fall outside the jurisdiction of the Insurance Commission. This has resulted in differing rules and regulations applied to various insurance products, and thereby created confusion in the market."[12]

"Due to the lack of rules to enforce the provision of the Cooperative Code, cooperatives were driven to provide various in-house insurance schemes to meet the needs of their members. However, these insurance schemes are unregulated, did not undergo any actuarial studies and may therefore be considered as unsafe and unsound. It exposes their members to further risks. More than 65% of total cooperatives registered with the CDA are no longer operating due to mismanagement, governance issues and more importantly, the lack of rules and regulations. Since most of these cooperatives have, in one way or another, informal insurance schemes, the need to come up with the necessary regulations becomes more apparent to protect their members' interests."

Aside from the HMOs, Philhealth can also utilize its leverage as the national health insurance provider to negotiate for quality, access, cost benefit and cost containment imperatives. By leveraging Philhealth's purchasing power, it can strengthen its influence over service provider behavior, drug cost, quality of services, etc. At present, Philhealth fails to consider this aspect of regulation and acts more like a reimbursement agency.

As a result of the inefficiencies of the regulatory authorities, health products, devices, facilities and services remain inaccessible to the majority of the Filipinos, particularly the poor. The upper class A and B can avail first class services, branded medicines, hi-tech laboratory tests from world class private tertiary hospitals in the urban centers. While the poor, particularly those in the far-flung rural areas resorts to substandard, poor quality, fly-by-night health facilities, medicines, and services. There are even those unreached Filipinos who have not seen any health facilities, health professionals, medicines, and devices- even those as basic as sphygmomanometer.

Current Initiative to Address the Problem

Given these concerns, the Department of Health is pushing for various reforms to strengthen the health regulatory authorities through stronger mandates, management and governance, augmentation of resources, capability and technological development.

Acknowledging the need for reforms, a new Food and Drugs Administration Law (RA 9711) was passed in June 2009 to strengthen the administrative, technical capacity, and resources of the drug regulatory authority. The law also indicated fiscal reforms within the FDA to encourage growth and development in technical capacities through increase in user's fee and a business plan for investment.

With the introduction of the new law more funds can be utilized by the agency to gear up its capability to address the various issues. It now faces and evolves towards a more effective regulatory agency in compliance with ASEAN Harmonization standards.

The challenge so far, is the delay in crafting the implementing rules and regulations which remains in the draft stage. Moreover, at the moment, FDA is headed by an interim director general but only as the Officer-In-Charge

designate. Because of this situation, more in-depth and substantive reforms might not be undertaken unless the political mandate is clear and the position and title is officially made.

The other recent piece of legislation is RA 9502 passed in June 2008. The government imposed a mandatory and voluntary drug price reduction. Moreover, it complements the Generics Act of 1998, for it also requires and ensures the production of an adequate supply, distribution, use and acceptance of drugs and medicines identified by their generic name.

However, the law remains inadequate. The law requires greater collaboration amongst the regulatory and other concerned agencies particularly Philhealth. Philhealth needs to take advantage of its leverage and the provisions of the law to reinforce greater compliance amongst the providers and the industry.

Conclusion: Alternative Interventions for Regulatory Reforms (Universal Health Care)

The analysis of the predicaments of the health regulatory system depicts complex and systemic problems which entail dynamic and systemic approach for the solution.

Integrative Framework and Harmonization of Regulatory Mechanisms

There is a need to address the fragmentation of the regulatory system and the health system itself. An overarching and integrative framework of Universal Health Care should be reinforced amongst health regulators both at the national and local level. Regulatory authorities should be working hand-in-hand to ensure provision of comprehensive and quality health care. A good facility alone will not deliver good health services. It should be complemented by adequate and competent health care providers, with equipment, medicines at affordable cost particularly for the poor. Ensure coordination amongst regulatory tools of each agency. For example, exploring areas for Philhealth's roles both as the main purchaser of health goods and services. It can leverage its position to lower costs and ensure quality, thus assuming quasi-regulatory functions.

Strengthen the Regulatory Authorities and Harmonize Mechanisms

Strengthen the mandate, system, regulatory tools, systems and resources of the regulatory agencies. Give the regulatory agencies quasi-judicial powers to ensure compliance of the private sector. However, it must also be ensured that accountability and transparency should also improve. Put information technology systems and performance management systems in place to enhance efficiency and transparency in transaction.

Deputizing the LGUs

Intensive efforts are needed to educate devolved local government health systems to understand their role in health regulation. Health regulation should not be the sole responsibility of national agencies. LGUs have an important stake in protecting the health of their constituents. Short of analytical testing, there are many ways that LGUs can ensure quality, such as supplier prequalification, physical inspection, supplier performance monitoring, good storage practices, and rational drug use. This also recognizes the fact that drug quality is more than analytical testing.

Involve the Private Sector and Educate the Consumers

The private health care system (clinicians and hospitals) have to be informed and made to appreciate that the selection of essential medicines has to be tightly regulated and cost and price are part of a clinical decision tree. They have to accept other payment mechanisms such as case payment instead of fee for service. DOH-retained hospitals must be reminded of AO 137: Waiver of Excess Fees and Charges for Philhealth Indigent Patients in All DOH-retained hospitals. Failure to justify the non-use of formulary (essential drug list) means disincentives from the NHIP in paying professional fees.[13] On the part of the consumers, they should be given the proper information with regards to their options. For example, intensify campaign for use of generics.

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