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ORIGINAL ARTICLE

Impact analysis of regulatory regime options for integrated health care provider networks in the Philippines

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ABSTRACT

Background: The enactment of the Philippine Universal Health Care (UHC) Act mandates the formation of Integrated Health Care Provider Networks (IHCPN), linking hospitals and health facilities, which includes government and privately-owned primary care providers. While hospitals and some health facilities are already under government regulation, primary care providers have not been subjected to formal licensing requirements. In this changing service delivery model, the possible impact of three regulatory policy options being considered need to be assessed according to the goal of ensuring that health services remain affordable and are of high quality.
Methodology: A multi-method approach to regulatory impact analysis (RIA) systematically assessed three regulatory options: 1) one Department of Health (DOH) license per hospital and health facility (status quo); 2) one DOH license for all public hospitals and health facilities within an IHCPN and another for individual private hospitals and health facilities; and 3) one DOH license per individual hospital and health facility, and one DOH certification issued to individual hospitals and health facilities as part of an IHCPN. Information from literature, documents, focus group discussions, and cost analyses were triangulated.
Results: Regulators are faced with two main risks: there is no standard for networked health care delivery that could provide a foundation for regulation, and provider participation is voluntary, which could lower the interest of private providers to integrate. The three regulatory options considered these risks. Option 1 requires the least change in regulatory policy, but is expected to increase costs to regulators due to the expansion of licensing and enforcement work covering primary care providers. Option 2 requires the most change in regulatory policy, but may be the least expensive to enforce, especially if all facilities join a network. This can also be preferred in a setting with existing interlocal health zones, and participation in the network by private providers poses the most challenge. Option 3 is a tiered regulatory set up that projects the highest cost to regulators as a result of both establishing new certification standards and guidelines on top of a wider scope for enforcement.
Conclusion: This is the first RIA conducted for the Philippine health system, with challenges similar to those experienced in developing countries. Across the three pre-determined regulatory models, the least costly option may not be the easiest to mount and enforce. Implementability appears to be a stronger consideration which seems to be hinged to the option requiring incremental rather than large form of changes.

Introduction

Health system regulation is defined as the *"use of effort by the state to alter the behavior of actors in the health system including providers, insurance companies, and patients"* [1]. Governments regulate health activities to: (a) establish a cohesive and efficient legal architecture for health system activities; (b) advance important health system policy objectives, such as universal access to services, establishing financial risk protection, or ensuring compliance with international obligations; and (c) protect the public from harm or from the adverse effects of unconstrained business activities in the health system [2].

Health regulation, therefore, engages systems involving pharmaceutical products, insurance packages, human resource credentials, and operations of hospitals and health facilities. Among the regulated health sector activities, hospitals and health facilities present a complex setting as it has to manage other regulated areas mentioned.

Philippine hospitals and health facilities are regulated by the Department of Health (DOH) Health Facilities and Services Regulatory Bureau (HFSRB), whose mandate is defined by Republic Act (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" [3], and DOH Administrative Order (AO) 2012-0012, "Rules and Regulations on New Classification of Hospitals and Other Health Facilities [4]." Hospitals are defined as "a place devoted primarily to 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 24-hour use or longer by patients in the treatment of diseases [3]." Health facilities are "institutions, whether stationary or mobile, land-based or otherwise, that provide any of the following services: diagnostics, therapeutic, rehabilitative, and other health care services except medical radiation facilities and hospital-based or stand-alone pharmacies [4]." Hospitals are classified according to ownership (government or private), scope of services (general or specialty), and functional capacity (level 1 to 3, specialty hospitals) [4]. Facilities are categorized into primary care facilities, custodial care facilities, diagnostics/therapeutic facilities, and specialized outpatient facilities [4].

Primary care facilities are first-contact health facilities that are responsible for gatekeeping to determine a patient's appropriate level of care. These facilities also provide core population services (maternal and child care, general internal and family medicine, ambulatory surgical care, etc.) based on population needs. Primary care facilities include local pharmacies, barangay health stations, rural health units, urban health centers, and laboratories, among others [5]. Both government and private-owned primary care institutional providers have never been previously licensed by the DOH.

Republic Act (R.A.) 11223 or the "Universal Health Care (UHC) Act" mandates hospitals and health facilities to form Health Care Provider Networks (HCPN), which prompted an examination of regulatory implications [6]. The HCPN is further described as a public, private, or mixed

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group of primary to tertiary care providers [6-8]. A primary care provider network (PCPN) serves as the foundation of the HCPN and is likewise composed of public or private primary care medical practitioners (rural health units, health centers, and outpatient clinics) that act as navigators and coordinators of patients that need referral to the higher level HCPN, which in turn would connect patients to an apex hospital when necessary. PCPNs can also link with pharmacies, laboratories, and diagnostic clinics that support the delivery of primary care services [6-8]. With the implementation of the UHC Act, every Filipino will be registered to a primary care provider with consideration of factors, such as proximity and preference.

Within this direction to integrate the service delivery involving hospitals and health facilities with specific attention to strengthening the participation of primary care providers, the DOH is considering options in regulatory policy with the goal of ensuring quality, affordable, and accessible health services. The DOH could opt to expand their current licensing regime being applied to hospitals and general health facilities, and use a similar approach to primary care providers. They could also consider shifting the regulatory licensing from individual hospitals, health facilities, and primary care providers into the proposed service delivery networks. In addition, the DOH could also consider combining these configurations and add relevant regulatory tools such as certification processes.

Regulatory activities must be justified and will fit the intended purpose. Unnecessary or poorly-designed regulations can result in inefficiencies, and poor quality regulation leads to an increase in compliance costs, unnecessary complexities, uncertainties in obligations, and the reduced ability of governments to achieve regulatory objectives [9]. To this end, RIA, or Regulatory Impact Analysis, a systematic and participatory process of identifying and assessing the effects of regulatory proposals through transparent analytical methods, is put forth. RIA compares regulatory options using a defined method to inform decision-makers on their implications [9].

The objective of this RIA, which began in 2019 and concluded in 2021, was to compare the possible policy consequences of applying different forms of regulation over integrated and networked health service providers. The DOH-specified options include expanding the scope of licensing (status quo) to include all participants of the network, licensing an entire network, and combining network licensing with individual facility certification. The policy impact to be assessed refers to the nature of risks and cost implications.

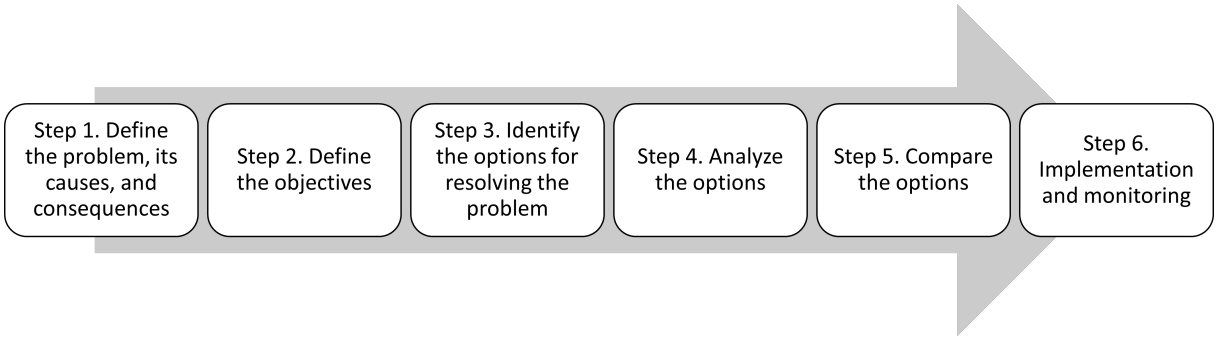

Figure 1. Regulatory impact analysis process [11]

Table 1. RIA objectives, process, constructs, and data collection strategy

Objective	RIA process	Constructs	Data collection strategy
Objective 1: To characterize the context of regulation on hospitals and health facilities	Step 1: Identify the problem	Expected role of hospitals and health facilities in the health system Anticipated performance issues in an IHCPN and its causes Impact	34 literature, policies, and documents reviewed FGDs in the three study sites and DOH Central Office
Objective 2: To assess the basic scenario and regulatory alternatives of regulating hospitals and health facilities by health care provider network	Step 2: Define the objectives	Goals of each regulatory option	
	Step 3: Identify the options for resolving the problem	Options deemed by the DOH as possible regulatory solutions	FGDs in the three study sites and DOH Central Office
	Step 4: Analyze the options	Direct economic cost of regulation to the government	Secondary analysis of Statement of Appropriations, Allotments, Obligations, Balances, and Disbursements of the Department of Health for 2019
Objective 3: To compare the cost analysis results of licensing of hospitals and health facilities by health care provider network	Step 5: Compare the options	Positive and negative implications of each option in a single framework for comparison	Review of literature FGDs in the three study sites and DOH Central Office Secondary analysis of Statement of Appropriations, Allotments, Obligations, Balances, and Disbursements of the DOH for 2019
	Step 6: Implementation and monitoring	Considerations to DOH in implementing and monitoring the options	Review of literature Discussion with DOH Insights from the study team

Health policy documents in the Philippines use "service delivery network and. From hereon, the phrase "integrated health care provider network" (IHCPN) will be used to link the local terminology to global literature.

Methodology

This process-based RIA was designed as a multi-method approach that was guided by a meta-process framework by Carvalho *et al.* (2016), which was formulated through a meta-analysis of 175 studies [10]. Each process was further specified by identifying questions related to the context of the RIA. The work of Marusic and Radulovic (2011) was also referenced as they provided insights in the conduct of RIA in low-resource settings (Figure 1) [11]. This complementary framework guided a six-step process that was used to fulfill the study objectives.

The RIA process is summarized in Table 1 (see Additional file 1 for detailed design). This multi- method RIA used document review, focus group discussions (FGDs), and quantitative estimation of the direct economic cost through the standard costing model to assess three regulatory scenarios as pre-determined by the DOH:

1. Option 1 - One DOH license per individual hospital and health facility (status quo);
2. Option 2 - One DOH license for all public hospitals and health facilities within an Integrated Health Care Provider Network (IHCPN) and one DOH license per individual private hospital and health facility; and
3. Option 3 - One DOH license per individual hospital and health facility and one DOH certification issued to individual hospital and health facilities as part of an IHCPN.

The study sites were purposely selected together with the DOH. The sites were earlier identified to be among the first set of UHC implementation sites and will move towards the formation of IHCPNs. Among these, one city and two provinces with prior experience of local system integration (i.e., inter-local health zone formation) were identified. This selection will allow a range in insights, within the bounds of project resources. Finally, DOH identified the areas where data about regulatory activities were available and accessible: Paranaque City, Batangas City, and Western Samar fulfilled these criteria.

A document review was conducted through an extensive search in several databases (PubMed, Google Scholar, SCOPUS, etc.) using relevant keywords, such as "hospital," health facility," "health service delivery network," "integrated health service delivery network," "health care provider network," "regulation," and "licensing" for documents published until 2019, including research, policies, technical reports, among others. Titles and abstracts were reviewed to identify which literatures were relevant to the topic, and duplicates were removed. References of selected literature were also reviewed for possible additional relevant literature. Selected literatures were then analyzed for information related to the objectives of the study.

The study targeted two FGDs with a maximum of five participants each with government regulators in the DOH Central and Regional Offices at the three study sites. Target participants were contacted through their official phone numbers and emails. Informed consent was sought from participants before each interview. FGDs were audio recorded upon permission as part of the informed consent process. Four (4) FGDs were conducted in October 2019 (three study sites) and March 2020 (DOH Central Office) with a total of 11 participants. Digital transcriptions of FGDs were produced a week after the conduct. These were transcribed in the language used during the FGDs.

Thematic and contextual analysis was used to synthesize findings from the document review and FGDs. These types of analysis were chosen due to the wide variety of research questions and topics that can be addressed with these methods [12]. The themes, codes, and categories of qualitative data were discussed among the research team before being finalized.

A standard costing model was developed using MS Excel to perform quantitative analysis. Costing inputs were sourced from the 2019 Statement of Appropriations, Allotments, Obligations, Balances, and Disbursements of the DOH. DOH HFSRB provided the 2020 Census of Health Facilities that were used as inputs in the model. Quantitative data were encoded and managed in MS Excel. Documentation records from this project were kept confidential between the project team and involved consultants. A health economist was consulted to determine the most appropriate analysis of quantitative data for the costing analysis. Triangulation was done to compare different sources of information.

Results

Table 2 summarizes the data sources. A total of 20 literature and 14 policies were reviewed for the study. Four FGDs were completed in the three study sites and the DOH Central Office. Costing data were received from DOH HFSRB in March 2020.

Characterization of the context of regulation: Identified risks (problems), causes, and consequences

Document review and the FGDs led to the identification of two regulatory risks or problems, its causes, and possible consequences.

Risk 1: Regulation is not yet designed, tested, and fully resourced in a network setup (Figure 2)

Current regulatory policies are focused on individual licensing of health facilities [3,4,13-16]. Network licensing is an untested form of regulation for health care providers in the country and the current regulatory regime is not designed for this. FGD respondents mentioned the lack of network-based standards and regulation guidelines, as well as the inadequate resources to license primary care facilities. This would include rural health units (RHUs) and barangay health stations (BHSs), which represent over 28,000 of health facilities in the country [17]. The inability to mount a fully resourced regulatory system to develop standards reflecting complex network arrangements and enforce these will lead to the difficulty in attaining regulatory goals such as quality of care. Yet, the other direction of maintaining regulation at the individual provider level can also be costly.

"How do you measure compliance of a network? As long as we have a metric, they can comply with standards."

Table 2. Summary of data sources

RIA step	Data sources
Step 1: Identify the problem	20 literature reviewed 14 policies reviewed
Step 2: Define the objectives	FGDs in the three study sites (October 2019) + DOH Central Office (March 2020)
Step 3: Identify the options for resolving the problem	Validated through FGDs with study sites (October 2019)
Step 4: Analyze the options	Secondary analysis of Statement of Appropriations, Allotments, Obligations, Balances, and Disbursements of the DOH from 2019 (completed on October 2019) Additional data received March 2020
Step 5: Compare the options Step 6: Implementation and monitoring	Data sources for Steps 5 and 6 were combined from those collected for Steps 1 to 4

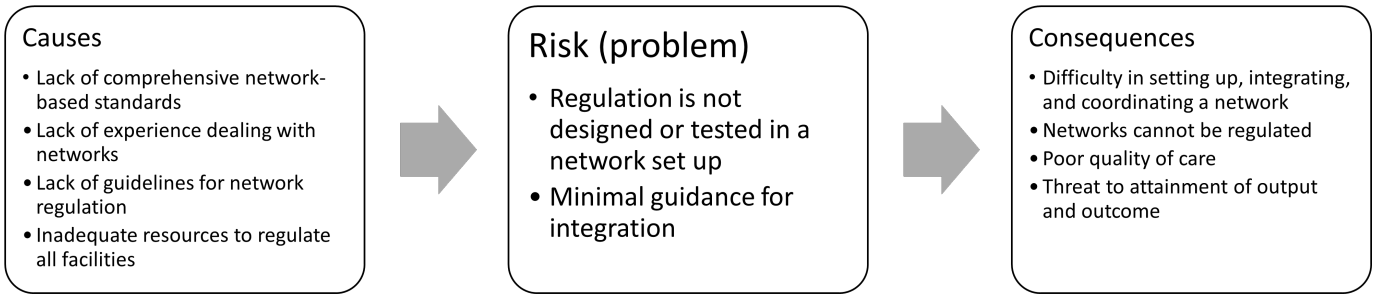

Figure 2. Problem tree for risk 1

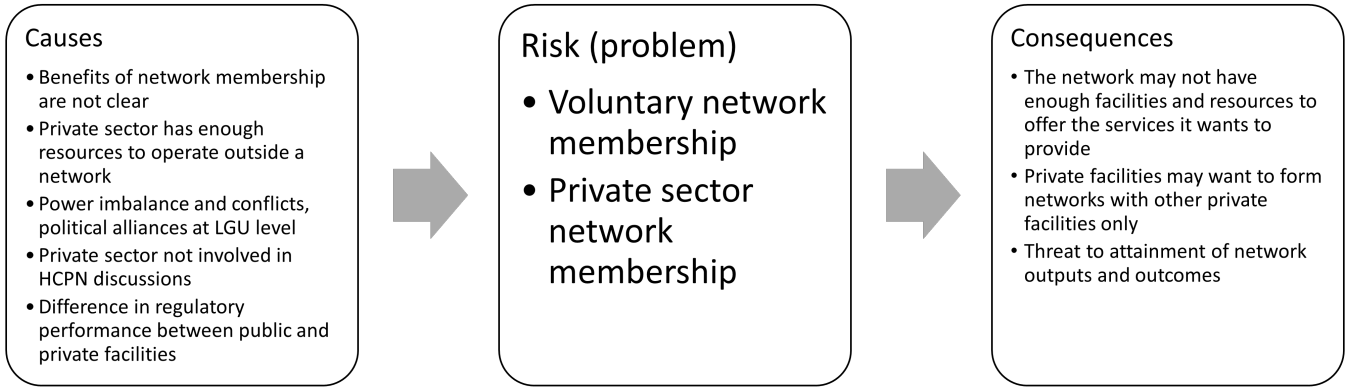

Figure 3. Problem tree for risk 2

"We would require more resources to regulate individual facilities. How do we regulate a network? But we would be requiring more than twice the amount of resources to regulate all facilities individually. We are expected to license around 4,000 facilities."

Risk 2: Voluntary and private sector network membership (Figure 3*)*

Another risk to the formation of IHCPNs is voluntary network membership which could pose lower participation of private providers in network integration. The extent of participation is unsure. FGD participants point out that there are unclear benefits of network membership for the private sector. For instance, one of the main aims of IHCPN formation is to pool resources across the network for healthcare delivery. Private facilities may not see the benefit of joining as they manage their resources differently and typically function well as standalone facilities. Another major cause of this risk is the current difference in regulatory compliance between public and private facilities. Given prior experience, one regulator respondent expects that private facilities would comply 75% of the time while only 50% from public facilities will likely do so. This could contribute to the hesitancy of private facilities to join a mixed ownership IHCPN.

Given this risk on the extent of participation by private facilities, the spectrum of services that an IHCPN wants to provide may be limited and affect the attainment of network objectives. This may result in private facilities wanting to form a privately-owned facilities IHCPN only, at least until public facilities demonstrate higher compliance to regulatory requirements.

"Some would be interested if there are benefits for them; some are not interested because they already have their own resources."

"Private sector may not want to join a network with public facilities. Networks may be exclusively public or private only. It may be possible once the performance of government networks improves for private facilities to join."

Regulatory objectives and tools of network regulation to address identified risks (Table 3)

Through document review and FGDs, the regulatory objectives and tools to support these were formulated to correspond to the components of the identified risks, its causes, and consequences.

Risk 1: Regulation is not yet designed, tested and fully resourced in a network setup

To mitigate this risk, policy review and FGD results point towards the design of an effective regulatory mechanism for a network. Regulation must sustain the current goal of providing quality services, patient safety and satisfaction, whether facilities are regulated as a network or individually [5-8]. FGD participants also expect network regulation to improve health outcomes, improve health human resource conditions and performance (due to decongestion of facilities), and improve provider satisfaction. Regulation must also monitor proper implementation, equitable distribution of resources, and cost-effectiveness of networks.

In a scenario where the network will be regulated, participants expect DOH HFSRB and regional regulatory offices to take on this regulatory role. Some tools that can support the implementation of the regulatory objectives are:

- Ability to establish and monitor service capability (human resource, equipment, infrastructure) within the context of IHCPNs
- Ability to assess performance and monitor functionality of IHCPNs
- Incentivize contracted IHCPNs based on their performance

Risk 2: Voluntary and private sector network membership

Strengthening of the network to encourage membership, as well as ensuring that facility members commit to their networks, were regulatory objectives identified from policy review and FGDs. Similar to Risk 1, this can be resolved through contracting apex hospitals, incentivizing health facilities to join a network, and incentivizing IHCPNs based on their performance.

Pre-identified regulatory options for IHCPNs

FGD participants identified how they expect IHCPN regulation to occur under the three pre-identified models proposed by the DOH HFSRB.

Option 1. One DOH license per hospital and health facility (status quo)

As facilities transition to networked service delivery, retaining the regulatory status quo may appear to be the easiest to implement. However, due to the additional facilities that need to be regulated as stipulated in R.A. 11223 and demonstrated in the National Health Facility Registry, primary

Table 3. Summary of regulatory objectives and tools of network regulation to address identified risks

Risk	Regulatory objective	Regulatory/non-regulatory tools to support objectives

Regulation is not yet designed, tested and fully resourced in a network setup	• Better health system performance
	• Population-wide health outcomes improvement
	• Improve access, efficiency, responsiveness
	• Reduce cost
	• Health systems strengthening
	• Provide quality services
	• Patient safety and satisfaction
	• Monitor implementation, equitable, and sustainable cost-effectiveness of networks
		• IHCPNs establish and monitor their service capability (human resource, equipment, infrastructure)
		• Center for Health Developments (CHDs)to assess performance and monitor functionality of IHCPNs
		• Apex hospitals enter into a Memorandum of Agreement with IHCPNs
		• Incentivize contracted IHCPNs based on their performance
		• CHDs to provide technical support to networks through
		  • Guide the development of IHCPNs
		  • Resolve issues, concerns, and problems on the development, utilization, and implementation of the coordination mechanisms within the network

Risk 2: Voluntary and private sector network membership	• Strengthen network to encourage membership • Ensure commitment of facilities to their network membership	• Incentivize health facilities to become part of IHCPNs • Issue LGU ordinance to govern public-private partnerships • Incentivize contracted IHCPNs based on their performance • Contract apex hospitals

care facilities will be difficult to license individually [6,17]. The regional-level Regulations, Licensing, and Enforcement Division will require additional human and financial resources to license the additional facilities. As such, FGD participants do not expect immediate implementation of regulating additional facilities due to immense resource needs. Participants expect that facilities that have been regulated prior to the UHC Act will experience no increased cost to compliance but primary care facilities such as rural health units may struggle to meet licensing requirements.

Option 2. One DOH license for all public hospitals and health facilities within an IHCPN and one DOH license for individual private hospital and health facility

In areas where interlocal health zones (a previous iteration of IHCPNs in the country [18] are functional, this option is preferred by FGD participants since networks are already formed. Participants suggested further that insurance incentives for healthcare providers through PhilHealth can be explored. Assuming that all facilities will be part of at least one network, licensing a network as a whole simplifies the regulatory process compared to the status quo. However, participants also recognize that the status quo will need to be maintained since facilities may choose not to join a network. In this case, facilities outside of a network need to be maintained on status quo licensing process. This implies that two regulatory models will be in place: one to license the IHCPN, and the other the status quo. Increased cost to develop network standards and to maintain two regulatory processes is expected.

Option 3. One DOH license for individual hospital and health facility and one DOH certification issued to individual hospital and health facility as part of an IHCPN

FGD participants see this option as an opportunity to introduce a two-tiered regulatory model where facilities are individually regulated twice. The first level involves status quo regulation and standards. The second level involves the provision of a network membership certificate upon compliance to higher network standards. This two-tiered model is expected to incentivize facilities to improve their compliance to qualify for network membership. This model is also expected to rationalize the number of facilities and facility types in one network. For example, since a network services a population within a geographical boundary, there must be a limit to the number of birthing homes needed in one network. Under this two-tiered model, the number of facilities within a network can be regulated. Since the certification signifies compliance to higher standards, these facilities will attract more patients. This can result in the closure of non-network facilities. Increased cost to regulators is expected for the development of network standards.

Costing the three regulatory options

Table 4 shows the total costs and cost savings of the current licensing regime along with the 3 proposed scenarios based on the Statement of Appropriations, Allotments, Obligations, Balances, and Disbursements of the Department of Health from 2019, specifically line items for Regulation of Health Facilities and Regulation of Regional Health Facilities [19]. The assumptions are based on the results of the preceding KIIs and FGDs and the National Health Facility Registry for the number of facilities [17]. Full details of the model can be seen in Additional File 2. The current cost of regulation without primary care facilities is estimated at PhP 244.7 million and covers 11,850 facilities. The highest estimated cost is Option 3 at PhP 496.1 million because it combined the cost of Option 1 and the additional cost of issuing certifications. Option 1 is higher than the status quo because of the addition of rural health units that need to be regulated. The option that costs the least is Option 2 at Php 181.2 million because there are less facilities to be regulated, assuming that all public facilities will be fully integrated into a network. It is also the option with the most benefit, with a cost-saving amount of Php 63.5 million. However, it should be duly noted that this assumes that transition costs are the same for all options, and that it only reflects the administrative costs to the regulator and excludes compliance costs for health facilities.

Comparing the options

Table 5 summarizes the pros and cons of the regulatory options.

Option 1 is the easiest to implement since it requires minimal changes in the regulatory policy and cost to compliance would be similar for the facilities. However, increased cost to regulators is expected due to the need to regulate additional facilities.

Providing one license per network (Option 2) is preferred in areas with an existing interlocal health zone since facilities are already formed in a manner similar to an IHCPN. When PhilHealth payments for facilities present enough incentives to voluntarily join networks, this could further support this regulatory option. Assuming all facilities will integrate in a network, this option is the least costly out of the three options.

A DOH certification (Option 3) is seen as a possibility to introduce a tiered regulatory set up. The status quo will be retained until such a time that a facility can comply with network regulation requirements. This can filter the number of necessary facilities per network. Consequently, this can potentially result in the closure of facilities with no certificate as certified facilities are perceived to be of higher quality by the general population. Certified facilities

Table 4. Comparison of the regulatory options

Option	Context and Assumptions	Total Number of Facilities / Network Regulated	Total Cost (Php Million)	Cost Savings (Benefit) (Php Million)
Baseline	• Derived from the 2019 Statement of Appropriations, Allotments, Obligations, Balances, and Disbursements (SAAODB) of the DOH specifically line items for Regulation of Health Facilities and Regulation of Regional Health Facilities. • An adjustment factor of 0.75 was used to account for efficiency of regulatory activities.	11,850	244.7	-
Option 1. One DOH license per hospital and health facility (status quo)	• Derived from the cost of licensing all the facilities and other additional costs such as policy development, training, and additional personnel. • Includes the cost of licensing additional primary care facilities such as RHUs [17].	14,442	330.4	-85.7
Option 2. One DOH license for all public hospitals and health facilities within an IHCPN and one DOH license for individual private hospital and health facility	• There is a maximum number of 54 public-led networks formed. • Only public health facilities are part of a network, and all of them are part of a network. • The cost of regulating networks was estimated using the cost of regulating Level 3 public hospitals as proxy. • Since private facilities are not part of the network, the cost of regulating them will remain the same.	54 Networks 6,928 Facilities	181.2	63.5
Option 3. One DOH license per individual hospital and health facility and one DOH certification issued per individual hospital and health facility as part of an IHCPN	• Estimated by combining the cost of Option 1 and the total cost of granting certifications to facilities that can comply with the standards of a network. • Since being part of the network is voluntary, it is assumed that 50% of total facilities will be complying to the network standards.	2,370 Accredited Facilities 14,442 Licensed Facilities	Accrediting facilities at 50% compliance 165 Cost of licensing individual facility + cost of accreditation 496.1	-251.4

are assumed to attract more patients in this model. Increased cost to regulators is expected in setting up new standards and guidelines.

Discussion

Regulation of integrated health care provider networks

The integrated delivery of healthcare services is an increasingly utilized management model to address the perceived gaps in health access across a continuum of care [20,21]. Integration, whether done horizontally (i.e. health facilities at the same level of care partnering to provide services to its patients) [22] or vertically (i.e. fulfilling patient needs on various health system levels through coordination of complementing health services) [23], is achieved through well-coordinated planning, financing, delivery, management, and organization of services [24,25]. One of the complexities of integrated health service delivery is attached to regulatory challenges [21]. An existing health system has a status quo regulatory regime—a current mechanism involving a set of stakeholders which ensures the safety and/or quality of service provision. Integration will introduce new partnerships, financial structures, and platforms to the health system. Thus, regulation must consider how and when it will exert knobs and incentives across the network.

It is important to note that most countries are in the early stages of integrating health services, and prescribing a single model towards regulation is not advisable [26]. Integration does not fit with a universal approach of regulation. In 2018, Brazil restructured their health care services to strengthen primary care and implement integrated network delivery. Inflexibility and lack of innovative regulatory policies is expected to be one of the biggest challenges in its regulation [27]. Similar to primary care networks in the Philippines, primary care services in Brazil are also expected to gatekeep patients. Regulation of the networks then became necessary, particularly access to care. Due to the context and focus on access to care in Brazil, the three proposed regulatory models are tailored towards the formation of a supply list for services offered by networks [27]:

- Scenario 1: Regional regulation
  - This model is expected to be implemented in regions capable of managing its own supply distribution and patient allocation according to demand, with consideration for capacity within the region. The region becomes responsible for patient flow and protocols.
- Scenario 2: Agreed or interregional regulation
  - One region becomes responsible for meeting resources in its own region and another according to prior agreements or quotas of care. Both regions must have similar health risks in its population. Dispensing of resources must follow prioritization guidelines according to population risk.
- Scenario 3: Central regulation
  - Involves resources rarely found in most regions, usually concentrated in the central supply system. The system supplies the region/s as a whole and regulation on demands, evaluation, and scheduling of flows happens at the central level.

The example from Brazil emphasizes the importance of context-specific regulatory design for integrated care. Lessons from high-income countries point towards flexibility and adaptation across contexts and settings [28]. Regulation must be effective, efficient, responsive, and foster compliance while limiting its burden on the system [29]. Older literature advises against a complete overhaul of the regulatory system as the task is simply too large to consider [30]. Beyond prescribing a set of standards, regulators should create a supportive regulatory environment and understand the capacity of local health systems to deliver the health needs of their intended population [31]. Finally, due to the voluntary nature of membership into the network, regulatory

Table 5. Comparison of the regulatory options

Regulatory option	Pros	Cons
Option 1. One DOH license per hospital and health facility (status quo)	• Since network membership is voluntary, this is the easiest option to implement. • Cost to compliance of facilities already licensed is the same to current set up.	• RHUs will be difficult to license individually. • Primary care facilities are not expected to meet licensing standards due to resource constraints. • Implementation of IHCPN regulation in this model may not be immediate due to immense resource needs by Regional Licensing and Enforcement Division (RLEDs) caused by additional facilities to be individually licensed.
Option 2. One DOH license for all public hospitals and health facilities within an IHCPN and one DOH license for individual private hospital and health facility	• In areas with functional Inter-local health zones (ILHZs), this option is preferred. • While membership is optional, facilities outside the network will not receive PhilHealth payments which will incentivize them to join a network. Assuming that all facilities will be part of a network, then this simplifies the regulatory process. • Assuming all facilities will join a network, this option is the least costly among the three options.	• Integration of facilities will be difficult due to variation in performance between facilities. • This option requires the maintenance of the status quo since network membership is voluntary. Facilities which do not want to join a network may require individual licensing. • This implies that two regulatory regimes will be in operation: one to license an entire network and the status quo. • In the case of non-compliance of just one facility in the network, it is unclear if the entire network will be affected.
Option 3. One DOH license per individual hospital and health facility and one DOH certification issued to individual hospital and health facility as part of an IHCPN	• This option can be part of a tiered regulatory scheme. In this scheme, non-network regulation compliant facilities can first improve their performance before finally being capable of being part of a network. The network certificate will be a higher regulatory tier than the License to Operate. • The issuance can filter the number of necessary facilities which can be part of the network. For example, there must be a limit to the number of birthing homes needed in one network which serves a certain population only.	• Can result in the closure of facilities not part of the network since the higher level certificate signals a higher quality to the population. • Most costly among the options due to the tiered regulatory scheme.

changes must consider how to entice membership of private providers [32-34]. Payment models must incentivize cooperation over competition and should be contingent on performance across the entire network [35,36].

Regulatory impact assessments in the Philippines

This study is the first regulatory impact assessment conducted at a health systems level in the Philippines. RIA appeared in public reports locally in 2012 and has been mostly used in the finance and labor sectors [37-39]. The implementation and quality of this RIA experienced challenges in data availability to properly assess impacts of the 3 regulatory options.

There is limited literature on the conduct of RIAs in low- and middle-income countries (LMIC). Evaluations of RIA systems in LMICs reveal an implementation gap with low level of sophistication. Partly, this may be because widely available RIA guidelines are from OECD countries and may not be directly applicable to developing countries [40]. Academic conversation and research on how to adapt RIA in LMICs has stalled, and practitioner-based literature is fragmented, contained within a small expert base [41,42]. While OECD best practices have had a major impact on international approaches to and concepts on RIA, the universality of its application to LMICs has been called to uncertainty [43].

The World Bank and OECD considers political commitment and institutional infrastructure to be essential elements of RIA in the context of developing countries [44-46]. However, attaining these two elements is a common challenge for LMICs [40,42,47]. In a survey of 16 developing economies, only Mexico has a longstanding RIA system. In the majority of the countries, including the Philippines, RIA is implemented on an ad hoc basis usually as part of a pilot phase in policy making [48].

The survey also found that RIA in LMICs suffers from severe capacity issues. RIA training is unsustainable in the long term as most are supported by international organizations [48]. Regulatory reform experts recommend that RIAs should reflect the existing expertise, resources, and information available in a country [40]. However, implementation and quality of RIA is hampered severely by the aforementioned constraints, as well as the lack of readily available data to properly assess impacts [42]. LMICs do not currently have the institutional capacity to undertake and effectively use RIAs, and experience difficulties with data-demanding methods [42,49,50].

Conclusion and Recommendations

This study resulted in the first regulatory impact assessment conducted for the Philippine hospital and health facility system according to recent DOH history. Across the three pre-determined regulatory models, the least costly option may not be the easiest to mount and enforce. Implementability appears to be a stronger consideration which seems to be hinged to the option requiring incremental rather than large form of changes.

The challenges and limitations encountered in this RIA are aligned with those experienced in other LMICs. As it is time-sensitive relative to changes also happening in the health system, we recommend the conduct of another study to acquire the perspectives of providers on network membership incentives, willingness to enter into a mixed ownership provider network, regulatory performance in a network, and cost of compliance based on the 3 regulatory options.

Results of RIAs are conceptually valid when decisions can be made within a reasonable timeframe while the assumptions included in the assessment remain unchanged. The context between the time that data was collected and the point at which it is received by policymakers as a decision-making tool should remain the same. It is difficult to take full advantage of a RIA when there is no system to internalize the recommendations and move it to decision-making. In the Philippine context, this may entail having an Administrative Order in place to articulate political commitment to utilize the results of RIA as a tool to guide decision-making.

Expectations from the RIA, its goals, and methodology must be aligned with available resources and data. For a more comprehensive RIA, data such as expenditure line items by activities and number of regulated facilities must be easily available or accessible. We recommend the inclusion of these data points in the annual report or monitoring and evaluation of DOH HFSRB and the Regional, Licensing, and Enforcement Divisions. The direct and indirect costs and quantified benefits of the regulators and providers/stakeholders should be accounted for to arrive with a balanced cost and benefit analysis and a more holistic policy recommendation.

Study Limitations

- In assessing the regulatory options for IHCPNs, the study simplified the variables which could not capture the full aspect of healthcare system complexity.
- The regulatory options assessed in this study are specific to the Philippine health system, and the conclusions might not be directly applicable to other countries with different health systems, political contexts, or resource availability.
- The findings from key informant interviews, focus group discussions, and costing analysis should be considered within the still evolving discussions of UHC reforms. Certain policy contexts may have changed by the time the study is published.

Ethics Approval

This study was granted a Certificate of Exemption from Ethics Review by the DOH Single Joint Ethics Review Board on 1 August 2019, SJREB-2019-28.

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