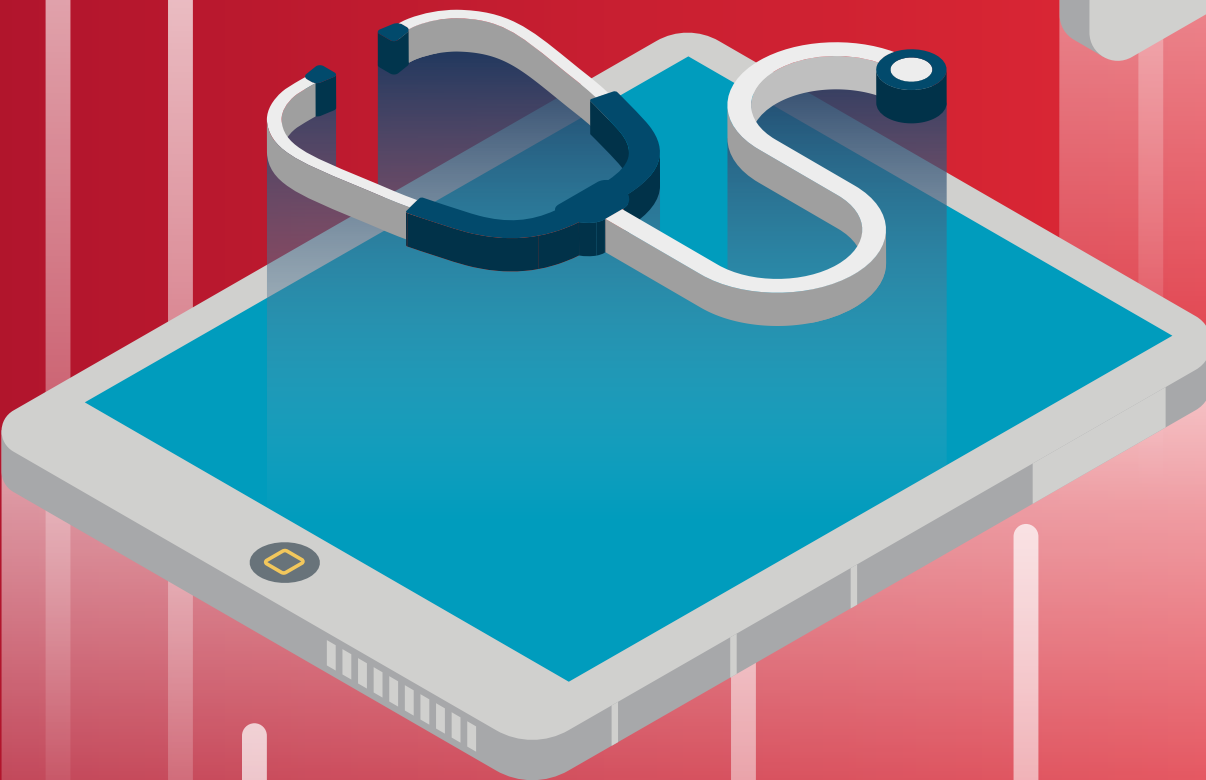


# Mobile Digital Health in the Philippines

Issues, Risks, Challenges  
and Opportunities

A WHITE PAPER | 23 OCTOBER 2019





# FOREWORD



Pru Life UK is proud to support this pioneering study that examines the present state of mobile digital health in the country while imagining the future of healthcare for Filipinos. A healthier population translates to lower protection costs. While there is generally greater public consciousness toward proactive and preventive healthier living, many challenges continue to beset the healthcare sector.

In Southeast Asia, the Philippines has one of the lowest per-person healthcare spending yet it is also the second most expensive in terms of medical expenses in the region. These problems are compounded in remote areas by the lack of medical facilities and infrastructure, high cost, lack of medical professionals, and a rise in mortality from chronic and infectious diseases. Under these circumstances, insurance costs including healthcare insurance, become too expensive for the average Filipino.

Mobile digital health is particularly beneficial to underdeveloped nations hampered by major limitations on healthcare due to lack of infrastructure, human and physical resources, and are burdened by poverty and disease. In the Philippines, it holds tremendous potential for improving healthcare by reducing costs and inefficiencies, improving accessibility and quality, promoting preventive measures, and making treatment more personalized.

As an organization that recognizes the wide interlinkages of health and its role as a driver of growth and development, we are expanding the scope of our commitment from ensuring financial protection against eventual losses from the deaths of family breadwinners, to investing more in the health and well-being of Filipinos. We are committed to narrowing the protection gap so that more Filipino families are protected.

Insurance penetration in the Philippines, defined as the total industry's premiums as a percentage of the GDP, remains low at 1.65% in 2017, according to the Philippine Insurance Commission. This rate barely scratches the surface of opportunities and is a testament to the sad reality that the benefits of insurance remain inaccessible to many Filipinos.

To compare, in the same year, the average insurance penetration of the world's 35 richest states, those belonging to the Organisation for Economic Cooperation and Development (OECD), was at 8.9%. Insurance penetration in our wealthier neighbors Singapore, Hong Kong and Malaysia were at 9.4%, 17.9% and 4.5%, respectively.

Pru Life UK's comprehensive vision towards health is to protect both health and wealth by leveraging on the Prevent-Postpone-Protect propositions. Prevent integrates lifestyle and wellness solutions; Postpone fuses disease management and recovery; while Protect blends triage, symptom diagnosis, and virtual health solutions with our offerings. Some of these value-added solutions will leverage on mobile digital health technologies and solutions. The use of technology in healthcare can address the gaps in resources and connectivity in the Philippines.

Designed to serve as a resource material on this still unexplored subject, we trust that this paper can spark and guide the much-needed and timely discussions for the crafting of thoughtful policies and regulations, and a new framework of implementation to facilitate further development of mobile digital health in the country.

A handwritten signature in black ink, appearing to read "Antonio De Rosas". The signature is stylized and cursive.

Antonio "Jumbing" De Rosas

President and CEO

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# EXECUTIVE SUMMARY

This paper aims to examine the current legal and regulatory framework governing Mobile Digital Health (“mHealth”) in the Philippines with the objective of identifying legal and regulatory risks, and recommend possible solutions on how to eliminate barriers to entry and integrate mHealth as part of the current reforms in healthcare in the Philippines. It also looks into the role of mHealth as a resource to promote, develop and uplift the current state of healthcare in the Philippines.

The term “mHealth” covers the use of applications or “apps” that are accessible through mobile wireless technology (i.e., mobile phones, tablets, laptops) for healthcare, in general. These applications cover various health services such as booking appointments with healthcare professionals (“HCPs”) online, online consultations with HCPs, electronic prescriptions of medicines (or e-prescription), navigating physical locations of hospitals and clinics, online ordering of medicines, recording and accessing patient diagnoses and information, tracking and recording daily diet and health lifestyle information, employing artificial intelligence to provide personalized health services, and accessing medical insurance products, information, and services (including filing and processing of claims).

Healthcare in the Philippines continues to face the challenge of lack of medical facilities and infrastructure, high cost, and lack of medical professionals. There is also a rise in mortality from diseases that can easily be prevented, such as heart and vascular disease, cancer, diabetes complications, and infectious diseases.

mHealth holds tremendous potentials for improving healthcare in the Philippines by reducing costs and inefficiencies, improving accessibility and quality, promoting preventive measures, and making treatment more personalized. The use of mobile devices is being leveraged by insurance companies to increase their interactions with customers and address the increasing demand for convenience and ease. It also allows insurers to reach underserved markets and offer more innovative products. In view of the Insurance Commission’s challenge to utilize technology and innovate, and the current industry initiatives to support programs in the healthcare sector, it is expected that life insurance companies will also contribute to the emergence and advancement of mHealth in the Philippines.

However, with more people having access to mHealth applications, and the growing complexities of the innovations in this area, we foresee a rise in regulatory issues and challenges, and the need for a clear and more refined regulatory framework.

The Philippines currently has no law, rule or regulation that specifically govern mHealth. The current legal and regulatory framework makes it difficult for innovators and business to widely introduce or grow the use of mHealth in the country. These issues include the lack of clarity on the categorization of certain aspects of mHealth that may be subject to nationality restrictions; regulations on the practice of profession, value-added services, medical devices, and online sale of medicines; consumer protection; intellectual property; and data privacy issues.

The lack of clarity in the rules, with several government regulatory agencies involved, makes it difficult for mHealth operators to comply. Current regulations do not address the specific features and technology involved in mHealth. For example, it is not clear whether mHealth applications may be deemed as medical devices. Likewise, there are no sufficient safeguards in place to protect the consumers who use these applications. Our current data privacy laws are also inadequate to protect health information from unauthorized access and abuse.

The recently passed Universal Healthcare Act (“UHCA”), which is seen to implement much-needed reforms in the

healthcare industry in the Philippines, offers an opportunity for the use of mHealth in advancing the aims of healthcare. The law aims to provide all Filipinos a comprehensive set of quality and cost-effective health services by mandating their membership to the National Health Insurance Program. The law also aims to adopt a unified government system in relation to health. It also institutes several reforms such as requiring members to elect a healthcare provider of choice, requiring healthcare providers to make available the list and prices of health services offered, requiring the establishment of an incentive-based rating system to health service providers, as well as pushing for preventive healthcare and health promotion. It visualizes a future where patient records are accessible throughout the health system and the development of a health information system.

The use of mHealth can help towards achieving the mandates of the law with its ability to (i) achieve faster and more efficient health information dissemination, (ii) track and process information to promote prevention, and (iii) make medical products and services available online and accessible to all Filipinos regardless of location. The data analytics capabilities of mHealth will also facilitate the collection and processing of patient records and health information, and help establish a comprehensive health information system in the Philippines.

To ensure that mHealth fulfills its promise of improving healthcare in the Philippines, Philippine regulators may consider the following recommendations:

1. formulate rules and regulations that will set concrete and practical tests to determine whether the operator or provider of mHealth platforms or applications is doing business in the Philippines;
2. clarify foreign equity restrictions to ensure that mHealth operators would not be deemed as engaging in mass media, advertising, or providing VAS;
3. introduce clear guidelines that will allow mobile consultation with medical professionals and online dispensing and selling of medicines;
4. issue a unified and harmonized set of regulations providing for the guidelines for digital health in general and mHealth platforms and applications in particular;
5. issue specific privacy guidelines covering the organizational, physical, system, and technical aspects of mHealth applications to reduce their risk of unauthorized use, processing, or access of personal data;
6. offer tax and other incentives for mHealth operators to introduce the innovation in the Philippines; and
7. integrate the data gathered and processed by mHealth applications into the health information system mandated under the UHCA.

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# I. INTRODUCTION

## OBJECTIVES

Through this paper, we aim to (i) examine the current legal and regulatory framework governing Mobile Digital Health or mHealth in the Philippines with the objective of identifying legal and regulatory risks, and (ii) recommend possible solutions on how to eliminate barriers to entry and integrate mHealth as part of the current reforms in healthcare in the Philippines. This also looks into the role of mHealth as a resource to promote, develop and uplift the current state of healthcare in the Philippines.

## METHODOLOGY

To achieve our objectives, we reviewed the current use and trends on mHealth, to understand how it can benefit the healthcare industry, and analyze the risks and issues arising therefrom. Our review was based on publicly available online journals, news articles, and other materials.

We also reviewed all relevant laws, rules, and regulations, as well as decisions of the Supreme Court and opinions of regulatory agencies, that may be relevant to mHealth in the Philippines, to understand their implications on mHealth, assess whether they are sufficient to address the risks associated with the trends that we see in mHealth, and identify the legal issues that may arise. We also examined the relevant regulations of neighboring jurisdictions in the region, for comparison.

## BACKGROUND

Digital health is broadly defined as the “use of digital technologies for health.”<sup>1</sup> The World Health Organization (“WHO”) defines “eHealth” as the “the cost-effective and secure use of information and communication technologies in support of health and health-related fields.”<sup>2</sup> The United States Food and Drug Administration (“US FDA”) defined digital health to include mobile digital health or mHealth, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine.<sup>3</sup> It covers the simplest use of technology in healthcare, such as the use of electronic medical records, to more sophisticated innovations, such as the use of artificial intelligence, robotics and big data analytics.<sup>4</sup>

mHealth is more specifically defined as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices.”<sup>5</sup> Generally, it involves the use of a mobile phone’s core utility of voice and short messaging service, as well as general packet radio service or GPRS, third and fourth generation mobile technologies or 3G/4G, global positioning system or GPS, and bluetooth technology.<sup>6</sup>

For the purpose of this paper, the term mHealth includes the use of applications accessible through mobile wireless technology (i.e., mobile phones, tablets, laptops) for healthcare in general. These applications may cover services such as booking appointments with HCPs online, online consultations with HCPs, electronic prescriptions of medicines (or e-prescription), navigating physical locations of hospitals and clinics, ordering of medicines online, recording and accessing patient diagnoses and information, tracking and recording daily diet and health lifestyle information, employing artificial intelligence to provide personalized health services (e.g., chatbots), and accessing medical insurance information, products, and services (including filing and processing of claims).

## BENEFITS OF MOBILE DIGITAL HEALTH

In general, digital health helps consumers make better-informed decisions about their own health. It provides them with more options to facilitate prevention, early diagnosis of diseases, and management of chronic conditions outside traditional healthcare settings. This is made possible through the use of software and technology that assist in diagnosis, treatment options, storing

and sharing health records, and managing workflow.<sup>7</sup> Consumers' use of digital health reduces costs and inefficiencies, improves access to options, improves quality, and makes treatment more personalized.<sup>8</sup>

The WHO has determined that mHealth, in particular, will augment the quality and coverage of healthcare, and improve access to health information and services.<sup>9</sup> It also promotes positive health-related behaviors that prevent acute and chronic diseases.<sup>10</sup>

The WHO has identified the following ways on how mHealth can be beneficial:

- increase access to quality health services “through the effective and timely sharing of health data,” especially populations that are hard-to-reach, and facilitating the easier gathering, analysis and exchange of health-related information;
- increase access to sexual and reproductive health services, including the reduction of maternal, child and neonatal mortality, by making related health interventions more accessible;
- reduce premature mortality from non-communicable diseases and non-communicable disease comorbidities by increasing awareness on key non-communicable diseases risk factors, improving diagnosis and maintenance of diseases, including chronic diseases;
- increase global health security by facilitating the culling of information directly from the public (i.e., crowdsourcing);
- increase safety and quality of healthcare by providing patients and doctors timely access to medical records especially in emergencies, disasters, and other instances where care is required; and
- increase patient, family, and community engagement by making people-centered health-related services.<sup>11</sup>

mHealth is particularly beneficial to underdeveloped nations where the use of mobile telecommunications is widespread.<sup>12</sup> These countries have major restrictions on healthcare due to lack of infrastructure, human and physical resources, and are burdened by poverty and disease. mHealth extends the reach of healthcare services by allowing Filipinos in remote and impoverished areas to access modern means of healthcare, without the need of physical infrastructure.<sup>13</sup>

mHealth is also helpful in managing non-communicable and chronic diseases. It focuses on preventive medication by helping in medication adherence, health literacy, the ability to self-manage, health awareness and other factors that may indirectly lead to better health.<sup>14</sup> The functionalities of certain mHealth applications are consistent with the current advocacies of the government of focusing on prevention over cure (promoting regular exercise and proper nutrition and addressing risk factors of non-communicable diseases).<sup>15</sup> Focusing on prevention would help bring down costs in healthcare.

mHealth also serves as an engagement tool that provides its users better access to health information, even for those residing in remote and hard-to-reach areas. System-generated SMS can also be used to widely disseminate health messages such as promotion of healthy behavior, surveillance, and management and treatment compliance of diseases.

It is also now being used as a tool to enhance patient engagement by matching patient needs and doctor capabilities, improving access to care and services, and making available personalized communications via the use of mobile applications.<sup>16</sup>

Technology used in mHealth allows the analysis of large amount of data in a relatively shorter time.<sup>17</sup> Artificial intelligence (in conjunction with big data analysis, robotics, and internet-of-things) is also used to predict possible disease outbreaks. A US-based company stated that it can predict outbreaks with an 81% accuracy.<sup>18</sup>

## MOBILE HEALTH STATISTICS AND TRENDS

The US FDA estimated as early as 2015 that around 500 million people globally are already using mHealth applications, and the number is predicted to grow rapidly to over 1 billion by 2018.<sup>19</sup> In a more recent survey, it was revealed that almost 83% of physicians in the United States are already using mHealth applications to provide patient care.<sup>20</sup> A study by Wolters Kluwer Health shows that 72% of physicians access drug information from smartphones, 63% access medical research from tablets, and 44% communicate with nurses and other staff through smartphones.<sup>21</sup>

In the Philippines, around 68% of the population will be using mobile phones by 2020.<sup>22</sup> The 40 million number of mobile phone users in 2016 will double to 90 million in 2021.<sup>23</sup> The percentage of mobile phones with access to long-term evolution (“LTE”) internet speed is also expected to grow from 5% to 70% by 2021.<sup>24</sup> Filipinos also spend the most amount of time online on a daily basis.<sup>25</sup> These statistics, and the proliferation of different mHealth applications accessible to mobile phone users around the world, highlight the inevitable growth and penetration of mHealth in the Philippines.

The most recent trend is the access of mHealth applications through fitness wearables. Fitness wearables not only track the physical activity (e.g., step count) and caloric intake of the wearers, they can also record sleep patterns and heart rates. The wearer may then access his/her health and lifestyle information through mobile phones and/or personal computers. Some wearables may warn its wearers of medical emergencies. In one instance, a fitness wearable saved the life of an 18-year-old teenager when her wearable advised her to “seek medical attention” due to elevated heartrate recorded in real time.<sup>26</sup> In another instance, the sluggish heart rate of the wearer, as indicated in his wearable, prompted him to visit the hospital, where the doctors discovered that his arteries were blocked.<sup>27</sup>

mHealth applications are also available on mobile or tablet devices. These applications have variety of uses, which include tracking personal health data (fitness tracking, sleep patterns, heart rate and other vital signs), and real-time communication with doctors or other HCPs, among several others.

mHealth is likewise helping bring efficiencies in the health insurance industry. mHealth applications are being integrated into wellness programs as a tool that can assist the consumers in monitoring health status and keeping them from accessing the health system unnecessarily.<sup>28</sup>

Another trend in mHealth is the integration of big data analytics, or the act of gathering and storing large amounts of information for eventual analysis<sup>29</sup>, in the healthcare industry, which is expected to grow up to \$34.27 billion by 2022.<sup>30</sup> It is projected that the use of big data in healthcare will grow faster than in other sectors like manufacturing, financial services or media, at an annual growth rate of 36% through 2025.<sup>31</sup>

### LIFE INSURANCE AND mHEALTH

Developments in mHealth in the Philippines will be shaped not only by traditional industry players (i.e., healthcare institutions and technology companies) but also by ancillary players that actively promote health and wellness, such as life insurance companies. The Insurance Commission (“IC”) has observed a proliferation of insurance products that promote a healthy lifestyle.<sup>32</sup> Further, according to Commissioner Dennis Funa, the IC anticipates insurance companies to innovate their products and services to incorporate the needs of their customers, particularly on the improvement of their overall health.<sup>33</sup>

One notable example is Prudential’s development of an mHealth application called Pulse, which integrates personal health management into the day-to-day lives of its users. The app contains the functionalities of health assessment, symptom checker, online consultation, offering health facts and tips, and fitness tracking services.<sup>34</sup> Pulse is a result of a collaboration with several other service providers such as Babylon Health, which provides symptom checker and health assessment services, Tictrac, which offers personalized wellness services, DoctorOnCall which allows online consultation with doctors, and AIME which is a dengue outbreak predictor. Prudential seeks to further expand the features of Pulse with the introduction of chronic illness management system, and insurance policy enquiry, claims and notifications.<sup>35</sup>

AIA offers Philam Vitality, a science-backed wellness programme that works with customers to help them make real changes to their health.<sup>36</sup> Philam Vitality allows customers to conduct online health assessments, including health review, online nutrition assessment, and mental wellbeing assessment. Further, it aims to make healthy living more affordable by providing discounts at fitness and wellness partners.

As regards innovation in the insurance sector, IC Commissioner Dennis Funa has recognized the rise of “insurtech” and “healthtech” as game-changers in the future of the insurance industry.<sup>37</sup> The IC is encouraging all IC-regulated entities to utilize technological advancements, as these are vital instruments in promoting financial inclusivity.<sup>38</sup> In light of the IC’s call for innovation and the initiatives of the life insurance industry to support the programs of healthcare sector, it is expected that life insurance companies will contribute to the emergence and advancement of mHealth in the Philippines.<sup>39</sup>

### CURRENT STATE OF HEALTH IN THE PHILIPPINES

The level of per-person healthcare spending in the Philippines is reportedly one of the lowest among Southeast Asia’s major economies.<sup>40</sup> In a survey, nearly half of Filipinos are unsure if they can afford hospitalization, while 30% are unsure if they can afford the cost of regular medical checkups. On the other hand, the Philippines is the second most expensive in terms of medical expenses in Southeast Asia, with medical inflation expected to continue to grow to up to 13.7% in 2019 from 13% in 2018.<sup>41</sup>

The physician to patient ratio of 1:1,000 is lower than the average in developed countries, and highlights the shortage of medical personnel in the Philippines. The actual numbers may even be lower because many licensed physicians no longer practice the profession or have migrated to other countries. The Philippine Medical Association only has around 70,000 active physician members that serve a population of 100 million Filipinos.<sup>42</sup> Adding to the problem is the fact that most HCPs are concentrated in urban areas like Metro Manila.<sup>43</sup>

Another problem is access to hospitals and medical facilities. Facilities in most hospitals in the Philippines pale in comparison with those abroad. Private hospitals have better technical facilities than public hospitals. There are 1,071 private hospitals and 721 public hospitals listed in the Philippines as of April of 2018.<sup>44</sup> A 2012 study of the Department of Health (“DOH”) and the WHO shows that only 4 of the country’s 17 regions meet the acceptable hospital bed to population ratio. Less than 50% or only 17,000 of the country’s 42,000 barangays have health centers.<sup>45</sup> The disadvantaged subset of the population are located in

remote and hard-to-reach areas, making it more difficult for them to access health services. Furthermore, only 59% of children in the poorest households are vaccinated, as compared to 81% in the wealthiest quintile.<sup>46</sup>

The leading cause of death in the Philippines is heart disease, which grew from 61 per 100,000 population in 1980 to 133 per 100,000 in 2014. This is followed by vascular diseases, malignant neoplasms, and chronic lower respiratory diseases. Death caused by diabetes also continues to grow. There is a notable shift in the leading causes of death from communicable diseases in the 1980s to non-communicable diseases in the recent years. This is mainly due to lifestyle changes of most Filipinos.<sup>47</sup>

In 2019, the Philippines still experiences epidemics and outbreaks of diseases. Early this year, the DOH declared a measles outbreak in the National Capital Region (“NCR”), other regions in Luzon, and in Central and Eastern Visayas.<sup>48</sup> This year, the Philippines experienced the worst dengue outbreak since 2012, where a total of 271,480 dengue cases were reported, and 1,107 have died as of August.<sup>49</sup> In September 2019, a polio outbreak was likewise declared.<sup>50</sup>

As mentioned, mHealth can help address the lack of access to healthcare facilities and healthcare professionals by allowing online consultations and prescriptions. This reduces costs and delays in treatment by eliminating the need to travel to hospitals. Mortality rate caused by preventable diseases may also be reduced through the promotion of disease prevention. Disease outbreaks may also be managed through artificial intelligence and connectivity capabilities of mHealth.

## ISSUES AND RISKS

Regulators around the world face the challenge of keeping up with the fast pace of innovations being introduced in various industries. Innovators also face the challenge of integrating their digital solutions into the highly-regulated healthcare industry. The fundamental challenge for any jurisdiction is to promote and facilitate the entry, development, and adoption of mHealth, and to regulate their use to protect consumer welfare.

The use of the Internet and digital technology also poses increased risk on data privacy and cybersecurity. Due to the personal and sensitive nature of health information culled through mHealth applications, data privacy is a key regulatory risk associated with mHealth. Health information may be monetized and abused by various entities without the consent of the data subject. The value of data and the vulnerability of the system also make them prone to hacking and other forms of data breach.

The increased use of mHealth devices and applications (e.g., wearables) requires regulation to ensure their reliability and accuracy. mHealth devices and applications should be ideally tested and regulated for the protection of consumers.

Further, as HCPs and hospitals move towards digitalization of their patient records, there are opportunities for allowing these information to be processed and used for various purposes to promote public health. This requires systems and processes to be interoperable.

## II. OVERVIEW OF EXISTING REGULATIONS IN KEY JURISDICTIONS

### SINGAPORE

The Health Sciences Authority (“HSA”) has made it clear that telehealth products may be regulated as medical devices, depending on their intended uses. The HSA’s *Regulatory Guideline for Telehealth Products* (“**Telehealth Guidelines**”) defines “telehealth” as the “provision of healthcare services over physically separate environments via infocomm technologies”. If a telehealth product is intended to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process, it is a telehealth medical device and is subject to HSA’s regulatory control.

A majority of healthcare services will soon be regulated under the Healthcare Services Act (“HCSA”), which will be implemented in three phases over the course of December 2019 to December 2020. The HCSA will be implemented by December 2020 to regulate non-premised-based healthcare services such as telemedicine services that have not been regulated under the existing *Private Hospitals and Medical Clinics Act*. Based on the *National Telemedicine Guidelines*, there are four domains of telemedicine: tele-collaboration, tele-treatment, tele-support, and telemonitoring. Where telemedicine is concerned, the Ministry of Health will only be regulating the provision of tele-treatment services, where the HCP makes a diagnosis or conducts follow-up treatment with the patient remotely.

### HONG KONG

There are currently no regulations that specifically govern mHealth in Hong Kong. The activities of mHealth, including telemedicine, are generally governed under the same framework for non-remote health or medical activities. No proposed regulations in this area are currently on the legislative agenda or expected to be introduced at this stage.

On the diagnosis, treatment, and/or monitoring of patients, the Code of Professional Conduct for the Guidance of Registered Medical Practitioners expressly provides that a doctor may prescribe medicine to a patient only after proper consultation. Prescription through mHealth is similarly subject to the same requirement absent further guidance. The Code also prohibits the promotion of individual doctors and their practice to people who are not their patients, as well as the sharing of professional fees by doctors with third parties. Breach of the Code could lead to disciplinary hearings, which may result in de-registration or suspension from practice.

The collection, use or transfer of personal data is governed by Personal Data (Privacy) Ordinance, which sets out general safeguards for the protection of personal data privacy applicable across all sectors. Other laws that may be relevant to the activities of mHealth are the Undesirable Medical Advertisements Ordinance (Cap. 231), Trade Descriptions Ordinance (Cap. 362) and Prevention of Bribery Ordinance (Cap. 201).

### THAILAND

In Thailand, a regulatory vacuum is also creating disincentives to investment in mHealth.

Under the Direct Sales and Direct Marketing Act (“DSA”), business operators that engage in direct marketing businesses are required to obtain a direct marketing license by registering with the Office of the Consumer Protection Board before commencement of business. Based on this broad definition of direct marketing, any sale of goods and services to customers

online (e.g., mobile application), which allow for real-time purchases by consumers (e.g., online sales of service via e-commerce application) would be deemed as engaging in direct marketing and is subject to a direct marketing license. Failure to obtain the direct marketing license can result to imposition of fines or penalties.

The Medical Profession Act and the Regulations of the Medical Council of Thailand on the Observance of Medical Ethics, which are the rules applicable to medical consultations, are silent on the provision of medical services online. On the other hand, the Drug Act, the main law governing the sale of drugs in Thailand, simply states that the holder of a drug sales license cannot sell dangerous or specially controlled drugs while the pharmacist is not on duty at the place of sale. So far as there is no prohibition, an e-prescription should be permissible as long as it includes the name and signature of the prescribing doctor.

The Personal Data Protection Act (“PDPB”) governs any data of a live person that could identify that person directly or indirectly. In order to collect, use, disclose, and/or transfer personal data, the data controller has to rely on legal basis, which could be consent or other exemptions (e.g., vital interest, public interest, legal obligations, and legitimate interest). As there is an extraterritorial application of the PDPB, an offshore entity could also be subject to the requirements under the PDPB if it is deemed a data controller or data processor who collects, uses or discloses personal data. The PDPA imposes penalties for non-compliance.

Furthermore, the National Health Act restricts the disclosure of personal health data, although the law does not provide for its definition. The law prescribes that personal health data shall be kept confidential and that no person shall disclose it in such a manner that may cause damage.

The Office of the Insurance Commission approved the utilization of a regulatory sandbox in Thailand to enable insurers, agents, fintech/insurtech players to test insurtech innovations.

## MALAYSIA

Among Southeast Asian countries, Malaysia is one of the very few countries with specific mHealth legislation, which it has been implementing since the 1990s. The primary legislation governing mHealth in the country is the Telemedicine Act, enacted in 1997. It aims to strengthen the healthcare delivery via use of telecommunications, information and multimedia technologies.

Under the law, telemedicine is defined as the practice of medicine using audio, visual, and data communications. It requires registered medical practitioners to first obtain a certificate to practice medicine before engaging in the same, which shall be valid for a period of three years. For practitioners outside Malaysia, the law requires both a practicing certificate and a certificate to practice telemedicine.

Malaysia’s regulations in relation to mHealth have the following features:

- address patient safety and quality of care based on data quality, data transmission standards or clinical competency criteria;
- protect the privacy of personally identifiable data of individuals, including those in digital format;
- protect the privacy of individual’s health-related data held in electronic format;
- govern the sharing of personal and health data between research entities;
- allow individuals electronic access to their own health-related data;
- allow individual to demand the correction or deletion of their health-related data; and
- allow individuals to specify which health-related data can be shared with health professionals of their choice.<sup>51</sup>

### JAPAN

There are currently no statutory laws that appears to specifically govern mHealth in Japan. However, medical devices and software for mHealth would be subject to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (“**PMDA**”).

The PMDA regulates manufacturing, selling, leasing, providing and offering of drugs and medical devices. Medical device includes programs which are (i) installed in physical devices and (ii) used for diagnosis, treatment or prevention of diseases or intended to have any effect on structures or functions of human body. Medical device does not include programs only for transfers, storage or display of data collected via medical equipment or those for daily health management of consumers (such as a program which displays, transfers and stores weight, blood pressure and heart rate). Whether a program falls within the scope of the medical device definition needs to be considered on a case-by-case basis. Companies which manufacture and sell medical devices need to be registered or licensed by competent authorities (i.e., license for business). In addition to this restriction, the medical device needs to be approved for sale (i.e., license for products).

It is uncertain whether remote diagnosis is legally permissible in Japan. The Ministry of Health, Labour and Welfare (“**MHLW**”) issued an announcement stating that HCPs should principally provide face-to-face diagnosis. Remote diagnosis may be allowed as long as it is carried out to supplement the face-to-face diagnosis, such as when such face-to-face diagnosis is difficult due to location of a patient.

It can be seen that most countries in the region are still in the process of transitioning their current rules and regulation to accommodate mHealth, while some jurisdictions, like Singapore and Malaysia, have explicit efforts to answer and cater this new technology.



## III. LEGAL AND REGULATORY FRAMEWORK IN THE PHILIPPINES

Currently, there is no specific law or regulation that governs mHealth in the Philippines. Instead, certain features of mHealth are governed by several laws, rules, and regulations.

### A. ENTRY TO MARKET

#### DOING BUSINESS

The basic hurdle that mHealth operators must overcome is whether they will be considered as doing business in the Philippines, which would require them to obtain a license to transact business in the Philippines (i.e., directly as a branch or representative office, or indirectly through a subsidiary). The Foreign Investments Act of 1991<sup>52</sup> (“**FIA**”) defines what constitutes doing business, but this law has been enacted before the advent of online technology. Nevertheless, government agencies, such as the Securities and Exchange Commission (“**SEC**”), apply the framework of existing laws to online platforms.

The FIA defines “doing business” by enumeration. It essentially covers acts that imply a continuity of commercial dealings or arrangements, and the performance of acts or works, or the exercise of some of the functions that are normally incidental to, and in progressive prosecution of, commercial gain or of the purpose and object of the business organization.<sup>53</sup>

In an Opinion,<sup>54</sup> the SEC adopted the Sliding Scale Test to determine whether Internet businesses are subject to the jurisdiction of Philippine regulatory agencies. The test provides that the likelihood that jurisdiction can be constitutionally exercised is directly proportionate to the nature and quantity of commercial activity that an entity conducts over the Internet. Passive websites, which are only used to post information, do not generally generate sufficient contracts for regulatory agencies to exercise jurisdiction. Active websites, or websites that generate sufficient business over the internet, may be subject to the agencies’ jurisdiction. According to the SEC, a foreign online platform that offers for sale or is engaged in the selling of content and services over the Internet to account holders in the Philippines is considered as doing business in the Philippines. This is notwithstanding the fact that the company’s activities, employees, properties, and servers are located outside the Philippines.

Thus, the operation and maintenance of mHealth applications to users in the Philippines may qualify as doing business in the Philippines. Doing business without the necessary license may subject the entities involved to penalties. While they can be sued, they cannot sue to enforce their rights in the Philippines unless they obtain the requisite license.

#### NATIONALITY RESTRICTIONS

Certain aspects of mHealth operations may be subject to foreign equity restrictions.

##### a. Mass Media

Under the Constitution, mass media may only be owned and managed by entities that are 100% Filipino-owned and managed. Although the term “mass media” is not defined in the Constitution, the SEC interpreted mass media as including internet or online media platforms that disseminate information.<sup>55</sup> The SEC has likewise opined that an entity is deemed engaged in mass media if it disseminates information to the general public.<sup>56</sup> While the Internet per se is not mass media, it may be used as a digital platform or medium to disseminate information and ideas to the public, in which case, an online activity may constitute mass media undertaking.<sup>57</sup>

An online or mobile platform will not be deemed as engaged in mass media if:

- There is no pervasive or indiscriminate display to the general public of any promotional materials or advertisements on the products being offered by the third-party clients or even the platform or mobile app itself.
- Only the following are made available in the app, website or platform:
  1. enumeration of the services offered by the platform itself;
  2. instruction on how to use the said platform;
  3. enumeration of third-party partner, and thus shall only be limited to the listing of the name or logo of the third-party client; and
  4. any other information on the platform required to be disclosed by any law or regulatory measures.
- The disclosure of the products and services offered by its third-party clients is only for the purpose of completing the transaction enabled by the app, website or platform.<sup>58</sup>

Based on the foregoing guidelines, mHealth applications that post or allow access to third-party products and services may be deemed as engaging in mass media. This is a barrier to entry for foreign-owned mHealth applications because mass media is reserved for Filipinos.

### **b. Advertising**

The Constitution also imposes a 70% nationality restriction for those engaged in advertising. Like mass media, the term “advertising” is not defined in the Constitution. The SEC has defined advertising as “the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data, or information about the attributes, features, quality or availability of consumer products, services or credit.”<sup>59</sup>

mHealth applications may be deemed as being engaged in advertising if the operators prepare commercial messages or materials for third parties to be posted on the platform, or advise third-party clients regarding the dissemination of the latter’s commercial messages on the platform. Applied strictly, foreign-owned mHealth operators engaged in advertising will need to find a Filipino partner that will own 70% of the business, in order to operate in the Philippines.

### **c. Value-Added Services (“VAS”)**

VAS is broadly defined as “enhanced services beyond those ordinarily provided for by local exchange and inter-exchange operators, and overseas carriers through circuit-switched networks.”<sup>60</sup> National Telecommunications Commission (“**NTC**”) regulations define “enhanced services” as “services that improve upon the quality and/or functionality of services ordinarily offered by local exchange and inter-exchange operators and overseas carriers.”<sup>61</sup> The NTC regulations<sup>62</sup> enumerate specific services that are considered VAS, such as:

- Information service – includes all types of information delivered to/accessed by the user/subscribers (e.g., road traffic information, financial information, visa application information, and others of similar nature); and
- Applications service – includes all types of applications delivered to/accessed by the user/subscribers (e.g., mobile banking, electronic payments, point of sale service, etc.)

VAS providers are regulated if (i) VAS services are provided directly to the Philippine general public, and (ii) such services are provided for a fee. The NTC regulates the regulated VAS providers, in the same way as the NTC regulates public utilities, by limiting their foreign equity to 40%, and by requiring their registration as VAS providers with the NTC.

Based on the foregoing definition, mHealth services will most likely be considered VAS (*i.e., information and applications*

*services - specified above*). If the mHealth services would be offered for free, the same would not be subject to NTC regulations. On the other hand, if the public or end users would be required to pay a fee in order to avail of such services, then the same would be regulated and both the nationality and registration requirements must be duly complied with by the mHealth providers.

### **DISTRIBUTION AND SALE OF DRUGS**

The Food and Drug Administration (“FDA”) Act regulates the importation, distribution, sale, advertising, promotion and other marketing activities for health products, including drugs.<sup>63</sup> Entities that deal with health products are required to obtain a license to operate (“LTO”) from the Philippine FDA. Drugs must also be registered with the FDA. Only persons with a valid LTO can obtain registrations covering the drugs. Thus, mHealth operators cannot directly engage in the distribution of medicine without an LTO, and only registered drugs can be sold through the app. mHealth operators must engage third-party licensed drug establishments for the sale of drugs through the app. The FDA prohibits online selling of medicine without complying with the necessary regulations.<sup>64</sup>

### **PRACTICE OF PROFESSION**

mHealth applications that offer professional services such as medical consultations may also be subject to the rules applicable to the practice of profession in the Philippines. Under the Annex on Professions of the 11th Foreign Investment Negative List (“**Negative List**”), the practice of medicine and pharmacy are reserved to Filipinos and may not be practiced by a corporation. mHealth platforms that provide professional services must engage licensed Filipino professionals.

### **MEDICAL PRACTICE**

Under Philippine law, corporate practice of profession is prohibited and against public policy. In a case, the Supreme Court held that a hospital, as a juridical entity, cannot practice medicine, which is a profession.<sup>65</sup> The SEC also explained that personal qualifications for the practice of a profession cannot be possessed by a corporation, and in view of the distinct and separate personality of the corporation from the individual members or stockholders, a corporation could not have the power to do an act requiring a license which only individuals could obtain.<sup>66</sup> Thus, while a corporation can hire a professional for his services, the corporation itself cannot hire professionals for the purpose of carrying on the business of practicing a profession.

Under the Medical Act, a person shall be considered as engaged in the practice of medicine if he/she shall physically examine any person, and diagnose, treat, operate or prescribe any remedy for a disease, injury, deformity, physical, mental, psychical condition or any ailment.<sup>67</sup>

Thus, an mHealth application cannot undertake to practice medicine. An mHealth operator also cannot engage the services of doctors to provide services to the public. Any healthcare information provided in the mHealth application should not provide diagnosis, nor treat or prescribe any remedy for any condition, to avoid being considered as engaged in medical profession.

However, it would be possible for an mHealth operator to engage medical professionals as independent contractors, and use the mHealth platform to connect the patients directly to these professionals, who may then provide the diagnosis, treatment, and prescription, and answer questions in a clinical context. It would also be possible for mHealth operators to engage third-party telehealth operators to provide the telehealth functionalities of the app.

### **PRACTICE OF PHARMACY**

The Pharmacy Act regulates the dispensing of medicines in the Philippines.<sup>68</sup> Dispensing includes reading, validating and

interpreting prescriptions, preparing; packaging; labelling; record keeping; dose calculations; and counselling or giving information, in relation to the sale of transfer of pharmaceutical products, with or without a prescription or medication order.<sup>69</sup> The law recognizes “telepharmacy” services, which is defined as the services of a duly licensed pharmaceutical outlet done through the use of telephone, teleconferencing or facsimile.<sup>70</sup> Online pharmacy services is likewise recognized and defined to refer to pharmaceutical services of a duly licensed pharmaceutical outlet done over the Internet.<sup>71</sup>

Under the Pharmacy Act, one pharmacist shall have direct and immediate control and supervision over the outlet in order to dispense prescriptions and over-the-counter medicines, whether in-store or online. Virtual pharmacy without a licensed physical outlet is not allowed. The FDA guidelines specifically provide that online ordering and delivery, as well as mobile pharmacy, require prior application and prior approval of the FDA.<sup>72</sup>

### **INTELLECTUAL PROPERTY PROTECTION**

The Intellectual Property Code of the Philippines (“**IP Code**”) gives owners, authors, and developers of IP rights protection, primarily by granting them exclusive rights to use their creation or invention in trade or business, subject to certain limitations or restrictions.<sup>73</sup>

However, the IP Code does not specifically cover or address the peculiarities of mHealth applications. Generally, mHealth applications, specifically software, are not considered a patentable invention under the IP Code as it merely aims to digitalize provision of health services and does not employ an inventive step. Nonetheless, as with other existing mobile applications, the general provisions of the IP Code on copyrights and related rights may sufficiently apply and protect owners/developers of mHealth.

Owners and developers of computer programs or software used in mHealth shall own the copyright and economic rights associated in their creation, and shall have the exclusive right to reproduce the same. This protection is generally valid during the life of the author and for 50 years after his death.<sup>74</sup> Copyrights are protected from the moment of creation and registration with the Intellectual Property Office of the Philippines (“**IPOP**”) is not required in order for the copyright to be valid. In any case, owners of copyrights may deposit copies of their work with the National Library or the IPOPHIL.

## **B. REGULATORY FRAMEWORK**

### **REGULATIONS ON MEDICAL DEVICES**

The FDA Act<sup>75</sup> defines medical device to include an instrument, machine, software, material, or other similar or related article intended by the manufacturer to be used for human beings for the purpose of: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; or (b) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury, among others.

In 2014, the Philippines entered into the ASEAN Agreement on Medical Device Directive, which provides an almost similar definition for a medical device, which also includes software intended to diagnose and treat illnesses.<sup>76</sup>

Health products, as such medical devices, are required to be registered with the FDA and the manufacture, offering for sale, promotion, advertising of an unregistered health product is prohibited.<sup>77</sup> Under Administrative Order No. 2018-002, software used in medical devices and the medical device itself are subject to the additional requirement of software validation.<sup>78</sup>

mHealth applications may qualify as a medical device if they are intended to assist in diagnosing and treating health conditions. However, existing regulations, while covering software that serve as medical device (e.g., mHealth applications) are tailored towards physical and traditional medical devices. The FDA has yet to issue guidelines to allow stakeholders to implement and

transition to the new registration requirements. Under the old regulations of the FDA (which are still implemented), not all medical devices must be registered. Only those enumerated in orders issued by the DOH require registration. Based on the current list of registrable medical devices, mHealth applications are not registrable.

There are also additional requirements for “imported” medical devices, which fails to consider that software may be “imported” in a non-traditional sense (i.e., through the use of the Internet). mHealth applications developed and coded outside the Philippine are easily accessible to Filipino consumers without having to pass through the traditional mode of delivery.

### **CONSUMER PROTECTION AND E-COMMERCE REGULATIONS**

Under the Consumer Act of the Philippines<sup>79</sup>, consumer products and services cover goods and services primarily for personal, family, or household purposes, which shall include drugs and devices.<sup>80</sup> Under this broad definition, mHealth applications may be considered as a consumer product.

The Consumer Act regulates deceptive, unfair, and unconscionable sales acts or practices. Sellers of consumer products are likewise liable for imperfections in quality that render the products or services unfit or inadequate for consumption for which they are designed or decrease their value, and for those resulting from inconsistency with the information provided on the labels, publicity messages, or advertisements.<sup>81</sup>

The Electronic Commerce Act<sup>82</sup> acknowledges the validity and enforceability of electronic data message or electronic document.<sup>83</sup> The law upholds the validity of contracts entered into electronically.<sup>84</sup> The e-Commerce Act covers transactions executed through mHealth applications.

The E-Commerce Act punishes violations of the Consumer Act and other relevant laws committed electronically. The Department of Trade and Industry (“DTI”), DOH and DA issued Joint Administrative Order No. 01, Series of 2008 (“Joint AO 01”) which mandates retailers, sellers, distributors, suppliers, or manufacturers to provide (i) accurate, clear and easily accessible information to identify themselves, (ii) fair, accurate, clear and easily accessible information describing the products or services offered to enable consumers to make an informed decision, among others, and (iii) sufficient, clear, accurate, easily accessible information about the terms, conditions and costs of the consumer transaction.<sup>85</sup>

Joint AO 01 also requires covered entities to set up an internal complaint-handling mechanism for consumer complaints within a maximum period of three months.<sup>86</sup>

While Joint AO 01 modernizes the Consumer Act, its rules are still broad in application and do not take into consideration the complex nature of the services and products that are available through mHealth applications. For example, considering that the mHealth operator is not the seller of the products and services offered through the app, it is not clear as to who shall be required to comply with the requirements and liable for any violation.

### **ADVERTISING REGULATIONS**

The Ad Standards Council (“ASC”), created under the purview of the Consumer Act, is the advertising industry body in-charge of screening and regulating content of advertising materials across all mediums. It implements and enforces the Advertising Code of Ethics and Manual of Procedures, which was adopted by the Philippine advertising industry to promote efficiency in processing applications and resolution of cases.

Generally, internet and mobile advertisements are subject to a post-screening process, which is triggered by the receipt of a

complaint addressed to the ASC. However, advertisements which have leadership, superiority and exclusivity claim, as well as those with direct comparison, among several others, are required to be pre-screened. Likewise, advertisements of food supplements, health supplements, and dietary supplements shall be subject to the mandatory pre-screening process.<sup>87</sup>

The Manual of Procedures defines and covers Internet and mobile advertisements. Internet and mobile advertisements include SMS, MMS, e-blast, opt-in, spam messages, broadcast messaging service and other similar promotional ads except corporate websites. Based on the foregoing, it would appear that advertisements on mHealth applications will be subject to the regulations.

### **INSURANCE REGULATIONS**

The IC issued the Guidelines on Electronic Commerce of Insurance Products<sup>88</sup>, which regulate the issuance of insurance policy through electronic forms and online distribution of insurance products.

Under the IC E-Commerce Guidelines, insurance providers are not required to ask for prior approval for the establishment and roll-out of its system to support electronic commerce of insurance products. Nevertheless, the insurance company must comply with certain notification requirements, including submission of certain documents and information to the IC.

However, if the insurance company will use mobile applications for the distribution of insurance products, the insurance company will need to obtain prior approval of the IC before implementing such mode of distribution. Further, the mobile application or platform must be registered with major digital platforms like Apple, Inc. App Store, Google, Inc., and others.

At present, the prevailing regulations of the IC do not specifically cover the use of health technology (including mHealth) unless the same is offered in connection with the sale or distribution of an insurance product.

### **E-PAYMENTS REGULATIONS**

With the continuous growth of electronic payments or e-payments in the Philippines, because of the efficiency and convenience it offers to the public, it is likely that this system will be integrated into mHealth applications. This will subject the operators to additional regulations of the Bangko Sentral ng Pilipinas (“BSP”), especially if the mHealth application can be used to facilitate remittance activities.

The BSP regulates and licenses remittance and transfer companies (“RTCs”) or entities that provide “money or value transfer services”. Under prevailing BSP regulations on money service business operations, “remittance business” is broadly defined as “the transferring of funds or facilitating the movement of funds from the sender or originator to a receiver or beneficiary locally and/or internationally and undertaken by any financial institution.” RTCs include remittance agents, remittance platform providers, e-money issuers, and virtual currency exchanges.

The provision of a payment gateway facility may be considered a remittance business under BSP regulations. If the mHealth operator will engage in such an activity, it will need to register with the BSP as an RTC. On the other hand, if, (a) the mHealth operator will partner with a third party that is registered with the BSP as an RTC, (b) such third party will be the person or entity which provides the payment gateway facility, (c) the mHealth operator will not in perform any remittance business activity (including maintaining a settlement account to provide funds for remittance transactions within the LBU’s network), the mHealth operator need not register an RTC.

## **C. DATA PRIVACY AND PROTECTION**

The Data Privacy Act (“DPA”) protects data subjects from any form of unauthorized processing of personal information and sensitive personal information. The DPA defines “personal information” as any information, whether recorded in a material form

or not, from which the identity of an individual is apparent or can be reasonably and directly ascertained by the entity holding the information, or when put together with other information would directly and certainly identify an individual.<sup>89</sup> “Sensitive personal information” refers to personal information such as those about an individual’s health.<sup>90</sup>

mHealth providers will generally require data subjects (i.e., end users) to give out their personal information (e.g., log in details, etc.). Moreover, it will also collect sensitive personal information such as those about an individual’s health. Thus, the provisions of the DPA, and the requirements set therein, will apply.

The DPA and issuances of the National Privacy Commission (“NPC”) (“**DPA Regulations**”) govern the collection, transfer, and other forms of processing of personal data. The provisions of the DPA Regulations have extra-territorial application, and may therefore apply even to processing of personal data done outside the Philippines.<sup>91</sup>

With respect to the processing of personal data of mHealth users, the owners/administrators of mHealth applications are considered personal information controllers (“**PIC**”). A PIC refers to a natural or juridical person, or any other body who controls the processing of personal data, or instructs another to process personal data on its behalf.<sup>92</sup> The following principles apply:

- a. In processing personal data, a PIC must adhere to the principles of transparency, legitimate purpose, and proportionality.<sup>93</sup>
- b. PICs are required to provide data subjects with a privacy notice which must sufficiently inform them that personal data pertaining to them is being, or has been, processed, including the existence of automated decision-making and profiling.<sup>94</sup>
- c. The DPA Regulations regulate the processing of personal information by generally requiring the PIC to obtain each of the data subjects’ prior, express, and recorded consent. In addition, since sensitive personal information are processed, the DPA Regulations require consent to be undertaken pursuant to a declared, specified, and legitimate purpose.
- d. As PICs, mHealth providers are required to have reasonable and appropriate organizational, physical, and technical security measures for the protection of personal data which must ensure the confidentiality, integrity, and availability of personal information.<sup>95</sup>
- e. mHealth providers may transfer or share personal data to third parties or to related companies, or outsource the processing of personal data to third party service providers. The DPA Regulations, however, require data sharing agreements and data outsourcing agreements to be in place. These agreements must contain required provisions which will govern the transfer and processing of personal data.
- f. PICs are required to notify the NPC and the affected data subjects of a Personal Data Breach involving sensitive personal information or any other information that may enable identity fraud. The notification should be made within 72 hours from the discovery thereof. In addition, covered entities are also required to report to the NPC a summary of documented security incidents and data breaches on an annual basis<sup>96</sup>, and they must also notify the NPC when automated processing becomes the sole basis of making decisions about a data subject.
- g. mHealth providers must appoint their Data Protection Officers (“**DPOs**”) who will be accountable for ensuring compliance with the DPA Regulations. An entity which operates in the Philippines and meets any of the conditions provided by the DPA Regulations is also mandated to register with the NPC.<sup>97</sup>

Non-compliance with the requirements of the DPA may expose a PIC to compliance and enforcement orders, cease-and-desist orders, temporary or permanent ban on personal information processing, payment of fines (though the NPC has yet to release its schedule of fines), and/or civil damages, when appropriate. It is also important to note that the responsible persons or officers may further be exposed to penalties of imprisonment and/or fines.

### D. UNIVERSAL HEALTH ACT

In 2019, the Philippines has enacted the UHCA<sup>98</sup>, a landmark legislation envisioned to reform the Philippine healthcare system.<sup>99</sup>

The UHCA, which aims to achieve the State policy of promoting the health of the people, mandates the adoption of (i) a healthcare model that provides all Filipinos access to a comprehensive set of quality and cost-effective health services, and (ii) a health framework that fosters a whole-of-system, whole-of-government, and whole-of-society approach in the development, implementation, monitoring, and evaluation of health policies, programs, and plans.<sup>100</sup> The government is mandated to guarantee that the distribution of health services and benefits provided for in the law shall be equitable.<sup>101</sup>

One of the most important features of the law is that it mandates all Filipino citizens to be automatically included into the National Health Insurance Program (“**NHIP**”) of the Philippine Health Insurance Corporation (“**PhilHealth**”), granting them immediate eligibility and access to preventive, promotive, curative, rehabilitative, and palliative care for medical, dental, mental, and emergency health services.<sup>102</sup>

Members of the NHIP will be categorized into two primary groups: direct contributors, where there will be premium contributions from payroll, and indirect contributors, which shall be fully subsidized from tax collections. All Filipinos, as members, are required to register with a public or private primary care provider of their choice from a list issued by the DOH.<sup>103</sup> In order to promote and encourage better services from the health facilities, the PhilHealth is required to establish a rating system under an incentive scheme to acknowledge and reward health facilities that provide better service quality, efficiency and equity, and recognize third party accreditation mechanisms.<sup>104</sup> The DOH and PhilHealth shall likewise incentivize HCPs that form networks.<sup>105</sup>

Under the law, the DOH, as the overall steward of healthcare, is mandated to strengthen national efforts in providing a comprehensive and coordinated approach to health development with emphasis on scaling up health promotion and preventive care. It is also mandated to focus on increasing health literacy on reducing non-communicable diseases.<sup>106</sup> In relation thereto, the DOH shall also endeavor to contract province-wide and city-wide health systems, which shall have (i) primary care provider network with patient records accessible throughout the health system, (ii) accurate, sensitive and timely epidemiologic surveillance systems, and (iii) proactive and effective health promotion programs or campaigns.<sup>107</sup>

HCPs are also required to make readily accessible to the public and submit to DOH and PhilHealth, all pertinent, relevant, and up-to-date information regarding the prices of health services and all goods and services being offered.<sup>108</sup> A registry of medical and allied health professionals, indicating, among others, current number of practitioners and location of practice, shall likewise be developed by the DOH and the Professional Regulation Commission (“**PRC**”).<sup>109</sup>

#### HEALTH INFORMATION SYSTEM

The UHCA mandates all HCPs and insurers to maintain a health information system consisting of enterprise resource planning, human resource information, electronic health records, and an electronic prescription log, which shall be electronically uploaded on a regular basis through interoperable systems. Related to this is the current Philippine Health Information Exchange Program being implemented by the government, which can serve as the base in developing the health system mandated by the UHCA.<sup>110</sup>

Existing eHealth regulations in the Philippines are primarily focused on the creation of an interoperable health database. DOH-DOST-PHIC Joint Administrative Order No. 0001-16 implements the Philippine Health Information Exchange (“**PHIE**”), which is a platform for secure electronic access and efficient exchange of health data and/or information among health facilities, HCPs, health information organizations, and government agencies.<sup>111</sup>



The PHIE is intended to facilitate ease of access of healthcare by integrating and harmonizing health data collected from various electronic medical record systems and private and public hospital information systems.<sup>112</sup> It will allow healthcare providers to share data and information to improve healthcare efficiency and reliability.<sup>113</sup>

Consistent with the Constitutional right to privacy and the provisions and requirements of the DPA Regulations, Joint Administrative Order No. 0002-16 or the Privacy Guidelines for the Implementation of the Philippine Health Information Exchange (“**JAO No. 0002-16**”) was issued to implement guidelines to balance the public health goals of the Philippines, with the data privacy rights of each Filipino.<sup>114</sup> However, a review of JAO No. 0002-16 shows that it merely reiterates the general provisions and requirements contained in the DPA Regulations, to apply to PHIE.

More specific requirements and guidelines are provided in the Health Privacy Code implementing JAO No. 002-16 (“**Health Privacy Code**”), which contains detailed and sector-related procedures and guidelines to ensure protection of data privacy in PHIE. It provides for rules on proper collection and processing, access, use and disclosure of health information in the PHIE system. It also provides for more relevant and more specific security measures to be observed by participants in the PHIE. Further, it also regulates the use of cloud services and social media, and provides for management of human resources, in relation to handling of health information. Lastly, it also requires the appointment of a DPO and proper notification and reporting of data breach and security incidents, and provides procedures in investigation of complaints filed before the Health Privacy Board.

This program of the DOH, DOST, and PHIC to provide better health information exchange in the Philippines would greatly help in providing healthcare to the public. However, to date, PHIE has only been envisioned as a platform for efficient exchange of health information between participating HCPs and patients. mHealth applications are beyond the current coverage of the PHIE.

## IV. LEGAL CHALLENGES

The Constitution provides that the State shall protect and promote the right to health of the people.<sup>115</sup> Furthermore, it provides that the State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential health available to all the people at affordable cost<sup>116</sup> and shall undertake appropriate health research responsive to the country's health needs and problems.<sup>117</sup> The State is also mandated to protect consumers from substandard or hazardous products.<sup>118</sup> The Supreme Court has already ruled that these provisions are self-executing, and thus, shall be enforceable on its own.<sup>119</sup>

The Constitution also recognizes the right to privacy, which has been defined as the right to be free from unwarranted exploitation of one's persons or from intrusion into one's private activities, and the right to be free from unwarranted publicity, or to live without unwarranted interference by the public."<sup>120</sup>

Pursuant to these policies and mandates, Congress has enacted several laws discussed above. However, the current legal and regulatory framework does not achieve the State policies laid down in the Constitution in relation to digital health and mHealth as (i) it restricts and potentially bars entry of mHealth operators in the Philippines, (ii) it insufficiently regulates mHealth applications, (iii) its interpretation and application to mHealth is uncertain, and (iv) it does not address the specific data privacy needs in relation to digital technology.

### **BARRIER TO ENTRY FOR FOREIGN INVESTMENTS**

For entities who wish to introduce their mHealth products in the Philippines there is the uncertainty of whether they will be considered doing business and would require primary registration with the SEC. Existing opinions of the SEC may consider operators of online platform as doing business in the Philippines despite the fact that all of its assets (including manpower, servers, and properties) are located outside the Philippines. The lack of clarity in the rules discourages foreign operators from offering their products to the market due to the possible exposure to administrative and civil fines and penalties.

Foreign investors who would want to enter the Philippine market will also have to comply with restrictive foreign equity limitations. Engaging on disseminating information to the public, for example, would make the mHealth platform or application a mass media activity, which is not open to foreign ownership. The same is true for advertising and VAS, which are also subject to foreign equity restrictions.

The full potential of mHealth, including the possibility of offering health services to the public remotely to benefit low-income families in rural areas who do not have access to health facilities, is also restricted by current laws on the practice of the healthcare profession. For example, the mHealth applications will not be able to directly offer medical consultation services unless it engages a third-party provider and complies with the regulations on the practice of profession. Likewise, mHealth applications will not be able to dispense and sell medicines online except through licensed third parties.

Lastly, despite the costs and risks involved in developing mHealth applications, current IP laws and regulations may not provide full protection, as software is generally not considered a patentable invention.

### **CONFUSING AND OUTDATED REGULATORY FRAMEWORK**

Under current regulatory framework, several government agencies may exercise jurisdiction over the operators of mHealth platforms or applications and third-party providers of products and services through the platform, depending on the nature of

their activities. They will likewise have to comply with the different regulations and reportorial requirements that each of these agencies may impose. These disjunctive regulations may also result in confusion and uncertainty as to which entity shall be liable to the users for harm or damages arising from the use of the mHealth application.

The rules and regulations currently in place also do not address the specific features and technology involved in mHealth. For example, the definition of medical device only includes a general inclusion of “software”, but existing regulations are tailored towards physical and traditional medical devices. Based on the current list of registrable medical devices issued by the FDA, mHealth applications *per se* do not appear to be a registrable medical device. Furthermore, the current rules and regulations aimed to protect the consumers are general in language and does not take into consideration the specific risks that may arise from the use of mHealth platforms or applications, focusing only on deceptive, unfair, and unconscionable acts or practices, and transparency in information, without considering the potential risks that these mHealth applications may pose to the public.

In the use of mHealth applications, sensitive personal information, such as an individual’s health condition, will be collected, processed, and used. Without proper organizational, physical, system, and technical security measures, these data are prone to unauthorized access and hacking. This highlights the need for regulations tailored specifically to mHealth applications, not only to facilitate its introduction in the Philippine market, but also to ensure its safety and reliability.

In a survey study conducted by the WHO on eHealth, participated by 112 member States, a vast majority equaling to around 83% reported that there is at least one mHealth initiative in their country.<sup>121</sup> And of these 83%, it was reported that most are implementing four or more types of initiatives. Although the Philippines has reported a program on mHealth (e.g., emergency toll-free telephone service), it does not specifically answer the issues and challenges involved in the introduction of mHealth in the Philippines.

Executive Order No. 27, series of 2017, has been issued to direct all heads of departments, offices and instrumentalities of the national government to align their budgetary and departmental/corporate programs with the strategies and activities identified in the Philippine Development Plan for 2017 to 2022 (“**PDP Plan**”) approved by the National Economic Development Authority on 20 February 2017. Among the strategies and activities identified in the PDP Plan is to invest in e-health and data collection mechanisms for decision-making to address data gaps. In view of the above, government agencies should be encouraged to update current rules and regulations to advance the strategies of the Philippine government under the PDP Plan relating to healthcare.

## V. OPPORTUNITIES

The use of mHealth applications can help advance the mandate of the DOH under the UHCA to focus on health promotion and preventive care. As discussed above, mHealth has been shown to promote medication adherence, health literacy, self-management of disease, awareness and others. Thus, one big step that the DOH can do is to reconsider laws and regulations and encourage the introduction of mHealth in the Philippines, thereby promoting preventive healthcare among Filipinos.

Current features of mHealth also allow for hospital and clinic navigation that will make it easier for patients to choose the healthcare provider of their choice, as provided under the UHCA. Giving the consumers a catalogue of available HCPs will help them make more well-informed decisions. This is also in consonance with the registry of medical professionals mandated by the law, which can likewise be developed through a mobile platform. The mandate to the DOH and PhilHealth to rate HCPs can also be made easier and more convenient through the use of mHealth. The fast and reliable sending of information online, and the large number of users with mobile phones, will make the system more inclusive and useful.

Furthermore, information dissemination of health campaigns will likewise be easier as mHealth is capable of transmitting messages to a huge number of the population in a shorter amount of time. It will also make it easier for HCPs to comply with the mandate to make public all the health services they offer, as well as their respective prices.

mHealth will also help in achieving the state policy to make healthcare services available to all Filipinos, as it will allow Filipinos who are located in remote and hard-to-reach areas to avail health services through online consultation, e-prescription, online ordering of medicines, online symptoms tracking, and all other features that mHealth may, in the future, offer. An equitable and comprehensive healthcare system will only be made possible by making health services available to the marginalized sectors of society.

Analysis of large data generated by mHealth systems containing patient records will be possible through big data analytics that mHealth applications can facilitate. This capability will likewise make possible the accurate, timely, and sensitive epidemiologic surveillance systems mandated by the UHCA through the use of artificial intelligence.

## VI. RECOMMENDATIONS

The relevant government agencies should endeavor to issue a comprehensive set of regulations that will specifically govern digital health, and mHealth in particular, and address the issues discussed above.

We suggest the following recommendations:

1. Formulate rules and regulations that will set concrete and practical tests to determine whether the operator or provider of mHealth platforms or applications is doing business in the Philippines;

Government agencies, particularly the SEC, should revisit their current rulings and opinions on determining whether or not an operator of an online and mobile platform is considered doing business in the Philippines. A blanket pronouncement that online and mobile platforms available and accessible in the Philippines may be deemed as doing business in the Philippines, despite the fact that the operations, assets (including servers), and employees are outside the Philippines, will make almost all operators of online and mobile platforms, including interactive mHealth applications, as doing business in the Philippines. Most mHealth operators only provide an online platform, that can be fully operated offshore, that allows third-parties to offer their products and services, and it would not be commercially viable for the platform operator to set-up a presence in the Philippines. Current rules and regulations should at least require some form of physical presence in the Philippines (e.g., establishment of an office in the Philippines, actual and explicit solicitation from customers in the Philippines, or location of servers in the Philippines) to be considered as doing business.

2. Clarify foreign equity restrictions to ensure that mHealth operators would not be deemed as engaging in mass media, advertising, or providing VAS;

Government agencies, particularly the SEC, should clarify their rulings and opinions to ensure that foreign equity restrictions pertaining to mass media, advertising, and VAS are not applied to mHealth operators. Considering that mHealth applications generally allow third-parties to post their products and services on the platform, and mHealth operators generally determine the lay-out and functionality of the platform, most online platforms, will be covered under the broad definition of mass media and advertising. Foreign equity restrictions should only cover entities whose primary purpose and business model clearly pertain to the operation of a mass media and advertising business, and not just ancillary or incidental to its operations.

Furthermore, government agencies should expressly carve out mHealth from the nationality and registration requirements of the NTC for VAS providers. mHealth operators only use existing telecommunications network that are already currently regulated and nationalized as public utilities.

3. Introduce clear guidelines that will allow mobile consultation with medical professionals and online dispensing and selling of medicines;

The DOH, in partnership with the FDA and the PRC, should update the rules and regulations on the practice of medicine and pharmacy. With the current problem of inaccessibility of health services and HCPs, government agencies should update existing regulations to leverage the efficiency and accessibility that modern digital technology offers. The danger of unsafe and unregulated practice of these professions, when made online or through mobile applications, can be addressed through specific regulations.

4. Issue a unified and harmonized set of regulations providing for the guidelines for digital health in general and mHealth platforms and applications in particular;

Government agencies that exercise regulatory jurisdiction over various aspects of an mHealth application should coordinate with each other and endeavor to develop a harmonized set of regulations that will comprehensively cover mHealth. It should include (i) clear and distinct regulations on the mHealth operator and the third-party entities that offer products and services through the app, and the responsibilities and liabilities of each with respect to compliance and in relation to the users, (ii) regulation on the quality and safety of the hardware or software used, (iii) tailored consumer protection regulations that will consider the nature of the industry. The regulations can be issued through a joint administrative order, which is common practice in the Philippines for multi-agency regulations.

5. Issue specific privacy guidelines covering the organizational, physical, system, and technical aspects of mHealth applications to reduce their risk of unauthorized use, processing, or access of personal data;

Specific rules and regulations on data privacy should be formulated for mHealth applications. While promoting the free flow of health information among HCPs and government health agencies, treatment of health information data should be different from treatment of other general data and information. Rules should consider, for example, the importance of health information (including patient records) in emergency cases where the life of a person is at stake or where privacy of health information is used to commit fraud against life and health insurance companies, without prejudice to the main goal of protecting health information and sanctioning its unauthorized access and processing.

6. Offer tax and other incentives for mHealth operators to introduce the innovation in the Philippines; and

In light of its potential to improve healthcare services in the country, the Board of Investment (“BOI”) should consider including mHealth as among the preferred activities under the Investment Priority Plan. Currently healthcare services are included but are limited to hospitals and certain healthcare facilities (custodial care facilities, diagnostic or therapeutic facilities and specialized out-patient facilities). This will encourage more investments and innovations on mHealth in the Philippines.

7. Integrate the data gathered and processed by mHealth applications into the health information system mandated under the UHCA.

The mandate of the UHCA to establish a more integrated, inclusive, and organized system of health information for the general population, as well as the current implementation of the PHIE, can be achieved more efficiently by integrating mHealth applications into the system, and incorporating the vast amount of useful data and information that will be collected and processed by these applications into the PHIE. This would help develop the PHIE to become a more integrated and comprehensive health information network.

Separately, the IPOPHIL should propose amendments to the IP Code on the treatment and protection of emerging technologies involved in mHealth, especially on software and systems, to provide more protection to developers in this industry.

In the long run Congress may likewise consider enacting a comprehensive law that shall govern eHealth in general, the same way that Malaysia and Singapore have enacted their own laws.

The integration of mHealth in the current healthcare framework in the Philippines would make the provision of health services faster, more efficient, affordable, accurate, accessible, personalized, and reliable. Integration of mHealth into the healthcare system would only be possible through a unified, responsive, and sophisticated regulatory framework that will allow, encourage and promote the use of mHealth applications in the country.

# TABLE OF ABBREVIATIONS

ASC	Ad Standard Council
BSP	Bangko Sentral ng Pilipinas
BOI	Board of Investments
DPO	Data Protection Officers
DOH	Department of Health
DTI	Department of Trade and Industry
FDA	Food and Drug Administration
HCP	Healthcare Professionals
HSA	Health Sciences Authority
IC	Insurance Commission
IPOPHIL	Intellectual Property Office of the Philippines
LTE	Long Term Evolution
NCR	National Capital Region
NHIP	National Health Insurance Program
NPC	National Privacy Commission
NTC	National Telecommunications Commission
PIC	Personal Data Controllers
PHIE	Philippine Health Information Exchange
PhilHealth	Philippine Health Insurance Corporation
PRC	Philippine Regulation Commission
RTC	Remittance and Transfer Companies
SEC	Securities and Exchange Commission
UHCA	Universal Healthcare Act
US FDA	United States Food and Drug Administration
VAS	Value-Added Services
WHO	World Health Organization



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- i. intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
    - a. diagnosis, prevention, monitoring, treatment or alleviation of disease;
    - b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
    - c. investigation, replacement, modification, or support of the anatomy or of a physiological process;
    - d. supporting or sustaining life;
    - e. control of conception;
    - f. disinfection of medical devices; and
    - g. providing information for medical or diagnostic purposes by means of invitro examination of specimens derived from the human body;
  - ii. which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
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## Quisumbing Torres

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