EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

SENATE

S. No. 1888

Introduced by Senator Francis "Tol" N. Tolentino

AN ACT
EXPANDING THE DEFINITION OF "MEDICAL DEVICE" TO INCLUDE HEALTH APPLICATIONS, FURTHER AMENDING REPUBLIC ACT NO. 3720, OTHERWISE KNOWN AS THE "FOOD, DRUG, AND COSMETIC ACT," AS AMENDED BY REPUBLIC ACT NO. 9711, OTHERWISE KNOWN AS THE "FOOD AND DRUG ADMINISTRATION (FDA) ACT OF 2009" AND FOR OTHER PURPOSES

Explanatory Note

Software and mobile applications have become a useful tool in improving one's health. They can help boost over-all health and well-being and provide valuable health-related information. These applications or "apps," which are easily downloadable and readily available in app stores, address a wide variety of health-related aspects, such as nutrition, sleep, physical exercise, stress management, and medication reminders.

Thus, the prevalence and impacts of the mobile health industry, also known as *"mHealth,"* have become undeniable. In 2017, in the United States alone, over 318,000 health apps were already readily available in top app stores, with more than 200 apps being added each day.[1] The Global Mobile Health (mHealth) Market Insights and In-Depth Analysis 2020-2027 forecasts that the value of the mobile health industry will exceed $311.98 Billion by 2027.[2]

In the Philippines, the health industry has also gone digital with the launching and utilization of health-related mobile applications. They are convenient, affordable, and easily

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[1] *Mobile Health Apps: Taking a Closer Look at Compliance* dated August 8, 2019; accessed at https://liquid-state.com/mobile-health-apps-compliance/
[2] *Industry Overview of Mobile Health (mHealth) Market Report* dated September 26, 2020; accessed at https://www.openpr.com/news/2143577/global-mobile-health-mhealth-market-insights-and-in-depth

accessible to consumers. Digital healthcare ranges from online medical consultation or telemedicine apps to health assessment and monitoring apps for both physical and mental health. Currently, the primary use for health apps is for contact-tracing, which is a key public health intervention against the novel Coronavirus 2019 disease (COVID-19) as these apps break the chain of transmission by identifying and isolating persons who came into contact with an infected individual.

The use of contact-tracing apps has been effectively utilized by other countries in battling the COVID-19 pandemic, such as Singapore with its TraceTogether app, Germany with its Corona-Warn-App, Australia with its COVIDSafe app, and France with its StopCovid app.[3]

In the Philippines, the application StaySafe.ph was recently launched as the official contact tracing program of the government. It has been described as a game-changer in the fight against COVID-19. As of 10 September 2020, there were two million Filipinos and some 3,000 businesses registered under the StaySafe.ph app.[4]

Indeed, digital health technologies are valuable tools in the management of the COVID-19 response by helping public health officials reach and deliver information to a vast number of people more quickly, efficiently, and effectively. However, the definition of medical devices under Republic Act (R.A.) No. 3720, as amended by R.A. No. 9711, remains outdated and archaic in contrast to the rapid advances of technology in the medical field. The law does not sufficiently contemplate applications and digital platforms which have become an integral part of medical products.

Hence, there is an urgent need to amend the law. If software and mobile medical applications remain unregulated, the diagnosis, treatment, or prescription of medicines through these applications could potentially result in life-threatening consequences. Moreover, without proper licensing and registration, claims against medical malpractice and civil liabilities could be painstaking and difficult.

This bill seeks to further amend R.A. No. 3720 in order to redefine the term "medical device" to emphasize the inclusion of software and health applications under such definition and clarify the jurisdiction of the Food and Drug Administration (FDA) over such medical devices.

In light of the foregoing, the passage of this bill is earnestly sought.

FRANCIS "TOL" N. TOLENTINO
Senator

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[3] *Contact tracing apps: A new world for data privacy* dated October 2020. Norton Rose Fulbright; accessed at https://www.nortonrosefulbright.com/en-us/knowledge/publications/d7a9a296/contact-tracing-apps-a-new-world-for-data-privacy

[4] *About 2 million Filipinos now registered in contact tracing app* dated September 10, 2020, CNN Philippines; accessed at https://www.cnnphilippines.com/news/2020/9/10/staysafe-contact-tracing-app-users-about-two-million-filipinos.html

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Senate
Office of the Secretary

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20 OCT 14 P1 :54

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AN ACT
EXPANDING THE DEFINITION OF "MEDICAL DEVICE" TO INCLUDE HEALTH APPLICATIONS, FURTHER AMENDING REPUBLIC ACT NO. 3720, OTHERWISE KNOWN AS THE "FOOD, DRUG, AND COSMETIC ACT," AS AMENDED BY REPUBLIC ACT NO. 9711, OTHERWISE KNOWN AS THE "FOOD AND DRUG ADMINISTRATION (FDA) ACT OF 2009" AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

Section 1. Section 10 (g) (1) of RA No. 3720, as amended, is hereby amended to read as follows:

"SEC. 10. For the purposes of this Act, the term:

"X X X

"(g) 'Device' means medical devices, radiation devices and health-related devices.

"(1) 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software **OR HEALTH APPLICATION,** material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment,

alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device 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.

"X X X"

Section 2. Section 10 of RA No. 3720, as amended, is hereby further amended to insert a new subsection (nn) to read as follows:

"SEC. 10. For the purposes of this Act, the term:

"X X X

"(NN) 'SOFTWARE OR HEALTH APPLICATION' AS USED IN THIS ACT, MEANS A MEDICAL DEVICE THAT CAN BE INSTALLED AND/OR OPERATED ON MOBILE PHONES, TABLETS, COMPUTERS, OR ANY OTHER COMMERCIAL OFF-THE-SHELF COMPUTING PLATFORM, WITH OR WITHOUT WIRELESS CONNECTIVITY. ITS FUNCTIONS SHALL INCLUDE, BUT ARE NOT LIMITED, TO ANY OF THE FOLLOWING:

- **a. CALCULATE MEDICINE DOSES FOR THE USER;**
- **b. DIAGNOSE A MEDICAL CONDITION OR DISEASE;**
- **c. GIVE THE USER AN INDIVIDUAL PERCENTAGE RISK SCORE OF HAVING A MEDICAL CONDITION OR DISEASE;**
- **d. PRESCRIBE CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE; OR**
- **e. DETERMINE CONTACT BETWEEN AN INFECTED PERSON AND A USER."**

Section 3. *Separability Clause.* If any provision of this Act is declared unconstitutional or invalid, other sections or parts thereof not affected thereby shall remain in full force and effect.

Section 4. *Repealing Clause.* All laws, decrees, executive orders, rules, and regulations, or parts thereof, inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Section 5. *Effectivity Clause.* This Act shall take effect fifteen (15) days after its complete publication in the *Official Gazette* or in at least one (1) newspaper of general circulation.

Approved,