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

The definition of medical devices under Republic Act (R.A.) No. 3720, as amended by R.A. No. 9711, remains outdated and archaic in contrast to the rapid advances of technology in the medical field.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.

Mobile health applications are receiving increased attention largely due to the global penetration of mobile technologies. Changes in mobile health and current healthcare delivery have been emerging that we need to study them in the context of regulation and its implications for the future.

The challenges in regulating developments in delivering health care includes balancing the demand to protect consumers from the risks of mobile health applications while at the same time taking advantage of technologies to improve healthcare delivery, quality and safety.

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 view of the foregoing, the immediate passage of this bill is most earnestly sought.

LUI S RAYMUND "LRAY" F. VILLAFUERTE, JR.
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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:

"XXX

"(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."
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:

"XXX

"(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.