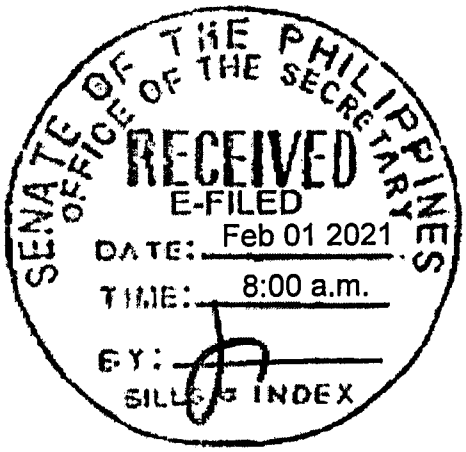


EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

SENATE

S. No. 2029

Introduced by **SENATORS VICENTE C. SOTTO III and PIA S. CAYETANO**

AN ACT
EXEMPTING MEDICATIONS AND VACCINES FROM CERTAIN PROVISIONS OF REPUBLIC ACT NO. 11223, OTHERWISE KNOWN AS THE UNIVERSAL HEALTHCARE ACT, DURING PUBLIC HEALTH EMERGENCIES

EXPLANATORY NOTE

Republic Act No. 11223, or the Universal Healthcare Act, provides for the health technology assessment (HTA) process, a priority setting mechanism that shall be recommendatory to the Department of Health (DOH) and Philippine Health Insurance Corporation (PhilHealth) for the development of policies and programs, regulation, and the determination of a range of entitlements such as drugs, medicines, pharmaceutical products, and other devices, procedures and services.[1] The law further provides that a positive recommendation from the Health Technology Assessment Council (HTAC) is needed before the DOH and PhilHealth can invest in any health technology or develop any benefit package.[2] One of the criteria that the HTAC must observe prior to making recommendations is that such a pharmaceutical product must have undergone Phase IV clinical trial, and systematic review and meta-analysis must be readily available.[3]

However, public health emergencies such as the COVID-19 pandemic require the State to act faster than what regular procedures allow in order to expedite the

[1] Section 34 (a), Republic Act No. 11223.
[2] Section 34 (a), Republic Act No. 11223.
[3] Section 34 (b) (2), Republic Act No. 11223.

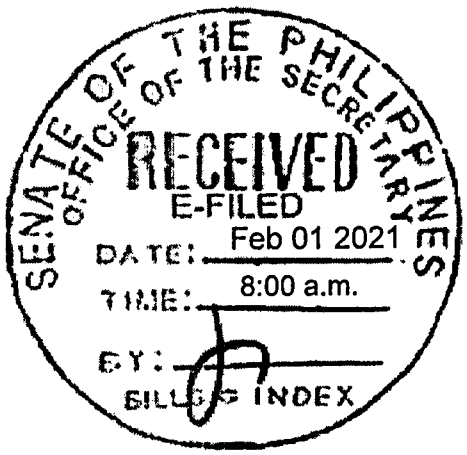
procurement of life-saving medications and vaccines. Currently, all available COVID-19 vaccines have not reached Phase IV clinical trials. It will take another two (2) to (5) years of further data gathering before reaching Phase IV. At present, some COVID-19 vaccine manufacturers have released preliminary data based on Phase III clinical trials. Emergency Use Authorizations have been issued around the world, based on the Phase III preliminary data. Republic Act No. 11223, which only allows HTAC to commence its review process based on data from Phase IV clinical trials, effectively limits the recommendatory power of the HTAC, and hinders the country's procurement efforts.

To this end, this bill seeks to authorize the HTAC to make recommendations on medications and vaccines to the DOH and the PhilHealth based on preliminary data from Phase III clinical trials and World Health Organization recommendations for a limited period, in the absence of completed Phase III and Phase IV clinical trials, during public health emergencies.

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

VICENTE C. SOTTO III

PIA S. CAYETANO



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

Section 1. *Short Title.* – This Act shall be known as the "*Agarang Lunas Laban sa Krisis Pangkalusugan Act*".

Sec. 2. *Declaration of Policy.* – It is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them.

Pursuant to this and the objectives of universal healthcare as provided in Republic Act No. 11223 or the Universal Healthcare Act, the State recognizes the importance of the health assessment technology process as a fair and transparent priority setting mechanism, adhering to the principles of ethical soundness, inclusiveness and preferential regard for the underserved, evidence-based and scientific defensibility, transparency and accountability, efficiency, enforceability and availability of remedies, and due process.

The State acknowledges that public health emergencies such as the COVID-19 pandemic necessitate the need for emergency processes in order to expedite the procurement of life-saving medications and vaccines. To this end, the State shall take proactive measures to fast-track the acquisition of medication and vaccines during public

health emergencies, while maintaining due regard for scientific evidence and consensus, quality healthcare, and the safety of all Filipinos.

Sec. 3. *Authority to Make Recommendations Based on Preliminary Data from Phase III Clinical Trials.* – Notwithstanding any law to the contrary, and upon the declaration of the President of a State of Public Health Emergency as provided in Republic Act No. 11332 or the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act", the Health Technology Assessment Council (HTAC) shall have the authority to make recommendations to the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth) on medications and vaccines based on preliminary data from Phase III clinical trials and World Health Organization recommendations, in the absence of completed Phase III and Phase IV clinical trials, during times of public health emergencies: *Provided,* That the medication or vaccine manufacturer has been issued an Emergency Use Authorization (EUA) by the Philippine Food and Drug Administration (FDA): *Provided, further,* That the HTA process shall only be valid for as long as the EUA issued by the FDA is in effect, such that in the event of revocation or cancellation thereof by the FDA Director General, the HTA process shall be terminated regardless of stage, and if it has been completed, the results shall be set aside: *Provided, finally,* That this authority shall expire five (5) years from the declaration of State of Public Health Emergency, or until such time that the President, upon recommendation of the DOH, declares the Public Health Emergency to be over.

Sec. 4. *Separability Clause.* – If any provision of this Act is declared unconstitutional or otherwise invalid, the validity of the other provisions shall not be affected thereby.

Sec. 5. *Repealing Clause.* – All other laws, decrees, orders, rules and regulations, other issuances, or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Sec. 6. *Effectivity.* – This Act shall take effect immediately upon its publication in a newspaper of general circulation or in the *Official Gazette.*

Approved,