

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 3049



Introduced by: Hon. Angelina "Helen" D.L. Tan, M.D.

AN ACT
PROVIDING REGULATIONS IN THE PACKAGING, USE, SALE, DISTRIBUTION AND
ADVERTISEMENTS OF ELECTRONIC NICOTINE DELIVERY SYSTEMS AND ELECTRONIC NON-
NICOTINE DELIVERY SYSTEMS (ENDS/ENNDS) AND HEATED TOBACCO PRODUCTS (HTPs).

EXPLANATORY NOTE

Electronic Nicotine and Non-Nicotine Delivery Systems (ENDS/ENNDS) and Heated Tobacco Products (HTPs) are rapidly emerging and diversified product class that typically deliver nicotine via an inhaled aerosol.

These products have become an increasingly popular choice among smokers, either on the assumption that such products pose less risk to conventional smoking-related diseases or that such products are smoking cessation aids. However, they are not completely harm-free. These products emit potentially harmful toxicants in the vapor if expressed at high levels.

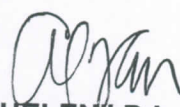
The seventh World Health Organization (WHO) Report on the Global Tobacco Epidemic, 2019 has recently warned that "ENDS pose risks to users and non-users", while "HTPs produce toxic emissions, many of which are similar to toxicants found in cigarette smoke" and must therefore be regulated. Hence, this bill provided some form of regulation for such products in order to protect and promote the right to health of the people and instill health consciousness among them (Article II, Section 15, 1987 Philippine Constitution).

As they are designed to mimic conventional cigarette smoking, initiation of non-smokers, especially the youth, to nicotine-dependency is a cause for concern. The use of products containing nicotine poses potential harm to youth with its addictive and teratogenic properties. Immediate action therefore must be taken at the national level to prevent access to what is commonly referred to as electronic cigarettes by the youth and regulation of its marketing should be made in such a way as not to attract minors. This will take the form of restricting age sales, prohibiting minor use, and policing marketing rules to ensure that promotions do not target minors as well as undermine smoking cessation messages.

More importantly, it prohibits the use of e-cigarettes in all public places and provides regulation on the sale distribution, and advertising of these products. This move is imperative in the face of reports of exploding batteries or defective electrical system which need to be addressed.

This bill will require ENDS/ENNDS and HTPs manufacturers, distributors, importers, exporters, and sellers to register with the Food and Drug Administration prior to market placement to ensure that such products have sufficiently passed quality and safety requirements and avoid untoward incidents to the public.

In the interest of public health and safety, immediate approval of this bill is earnestly sought.


ANGELINA "HELEN" D.L. TAN, M.D.
4th District, Quezon

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

SECTION 1. *Short Title.* – This Act shall be known as the "E-Cigarettes and HTPs Regulation Act."

SEC. 2. *Declaration of Policy.* – It is hereby declared the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Towards this end, the State shall implement measures to promote the general welfare by protecting the public against hazards to health and safety of electronic cigarettes, heated tobacco products, and similar products.

SEC. 3. *Definition of Terms.* – As used in this Act, the following terms shall mean:

(a) "Electronic cigarettes" refer to the most common prototype of ENDS/ENNDS. They are devices that do not burn or use tobacco leaves but instead vaporise a solution the user then inhales.

(b) "Electronic Nicotine and Non-Nicotine Delivery Systems" refer to combinations of non-tobacco containing e-liquids or refills and an electronic delivery device to produce an aerosol;

(c) "Heated tobacco products" refer to a form of tobacco products that uses an electronic device to heat processed tobacco leaves, and produces aerosols for inhalation by mimicking the behavior of smoking conventional cigarettes;

(d) "Vaping" refers to the act of inhaling and exhaling the aerosol, often referred to as vapor, which is produced by an e-cigarette or similar device; and

(e) "Young person refers to any person below twenty-one (21) years old.

SEC. 4. *Using ENDS/ENNDS and HTPs in Public Places.* – Vaping or the use of Electronic Nicotine, Non-Nicotine Delivery Systems, or electronic-cigarettes, and Heated Tobacco Products shall be prohibited in all places where tobacco smoking or the use of cigarettes is prohibited by law, executive order, or memorandum circular.

SEC. 5. *Designated Areas for Using ENDS/ENNDS and HTPs.* – In all enclosed places that are open to the general public, private workplaces and other places not covered by the preceding section, where the use of ENDS/ENNDS and HTPs may expose a person other than their user/s, the owner, proprietor, operator, possessor, manager, or administrator of such places shall establish areas for the use of ENDS/ENNDS and HTPs, which shall strictly comply with the following standards:

(1) There shall be no opening that will allow air to escape from such area to the prohibited area of the building or conveyance, except for a single door equipped with an automatic door closer; *Provided, That* if the area is not located in an open space, such door shall open directly towards a buffer zone or ventilated area between the door of such area not located in an open space and the area where the use of ENDS/ENNDS and HTPs are allowed;

(2) The area shall not be located in or within ten (10) meters from entrances, exits, or any place where people pass or congregate, or in front of air intake ducts;

(3) The combined area of the designated area and the buffer zone shall not be larger than twenty (20) percent of the total floor area of the building or conveyance; *Provided, That* in no case shall such area be less than ten (10) square meters;

(4) No building or conveyance shall have more than one (1) area for the use of ENDS/ENNDS or HTPs;

(5) The ventilation system for the area other than in an open space and for the buffer zone shall be independent of all ventilation systems and the rest of the building or conveyance;

(6) Young persons and pregnant women shall not be allowed inside the area and the buffer zone;

(7) The area shall have the following signages highly visible and prominently displayed:

(a) "ENDS/ENNDS/HTP Area" signage;

(b) Prohibition on the entry of persons below eighteen (18) years old and pregnant women.

However, there shall be no designated area for the use of ENDS/ENNDS and HTPs in the following public places:

(1) Centers of youth activity such as playschools, preparatory schools, elementary schools, high schools, colleges and universities, boarding houses, dormitories, youth hostels and recreational facilities for young persons;

(2) Elevators and stairwells;

(3) Locations in which fire hazards are present;

(4) Within the buildings and premises of public and private hospitals, medical, dental, and optical clinics, health centers, nursing homes, dispensaries and laboratories; and

(5) Food preparation areas

SEC. 6. *Minimum Age Sales.* – The following acts shall be prohibited:

(1) For any retailer to sell or distribute ENDS/ENNDS and HTPs to any young person;

(2) For any person to purchase ENDS/ENNDS and HTPs from a young person;

(3) For a young person to sell or buy ENDS/ENNDS or HTPs; and

(4) For a young person to use ENDS/ENNDS and HTPs.

It shall not be a defense for the person selling or distributing that he/she did not know or was not aware of the real age of the young person. Neither shall it be a defense that he/she did not know nor had any reason to believe that the ENDS/ENNDS or HTPs was for the consumption of a young person to whom it was sold.

SEC. 7. *Sale of ENDS/ENNDS and HTPs Within School Perimeters.* – The sale or distribution of ENDS/ENNDS and HTPs is prohibited within a minimum distance of one hundred (100) meters from any point of the perimeter of a school, public playground or other facility frequented particularly by young persons. Nothing in this provision or elsewhere in this Act shall be construed as limiting the powers of local government units (LGUs) under the general welfare clause.

SEC. 8. *Marketing Restrictions.* – No establishment shall manufacture, distribute, import, export, sell, offer for sale, and transfer ENDS/ENNDS and HTPs without first securing the necessary marketing authorization and License to Operate (LTO) from the Food and Drug Administration (FDA).

SEC. 9. *Restrictions on e-Liquids.* - The FDA shall set the appropriate standards and restrictions on flavors and additives used in the manufacture of e-liquids and refills. The FDA shall impose a ban on flavors and additives that are proven or suspected to be toxic, harmful, addictive, sensitizing, or appealing to young persons.

SEC. 10. *Restriction on the Retail and Sale of Nicotine Shots.* - The retail or use of nicotine shots and/or concentrates shall be strictly prohibited.

SEC. 11. *Restriction on Advertisement, Promotion, and Sponsorship.* - Any form of advertising, promotion, and sponsorship of ENDS/ENNDS and HTPs, including corporate social responsibility campaigns by the industry, shall be prohibited. No person, establishment, or organization shall use the FDA logo, the words "Food and Drug Administration" or "Philippine FDA", or any imitation of such words, initials, or logo in print and other forms of broadcast, media, including the internet, in connection with any ENDS/ENNDS and HTPs, merchandize, impersonation, solicitation, or commercial activity in a manner that convey that such use is approval, endorsement, or authorization by the FDA.

Placing, posting, or displaying ENDS/ENNDS and HTPs advertisements and promotion items including ENDS/ENNDS and HTPs in any place, except for the placement of a single simple sign with white background and black font and not exceeding twelve inches by eighteen inches (12"x18") in size stating only the following: ENDS/ENNDS/HTPs Available Here" inside point-of-sale establishments.

Promoting, directly or indirectly, ENDS/ENNDS and HTPs in an event, activity, program or project where ENDS/ENNDS and HTPs company is a participant as facilitator, sponsor, contributor, donor or benefactor, whether or not the same is part of its corporate social responsibility activities.

Engaging in any form of ENDS/ENNDS and HTPs advertisement and promotion, including advertising in social media, online media, and the internet.

SEC. 12. *Warning on Packaging.* - Containers and packages of ENDS/ENNDS, HTPs, e-liquids and refill shall contain appropriate health warnings. Nicotine containers shall bear textual health warnings with the following warning: "This product may damage your health and is addictive."

The health warning shall occupy thirty (30) percent of the lower part of the principal display surface of the nicotine container.

SEC. 13. *Role of the Department of Health and the Food and Drug Administration.* - The Department of Health, in consultation with the FDA, the Department of Trade and Industry, and concerned agencies, shall promulgate rules, regulations, and standards on packaging, ingredients, graphic health warnings, detailed information on the allowable nicotine-containing e-liquid, the strength of e-liquids, compliance with applicable electrical standards as well as with applicable industry standards for batteries.

The FDA shall monitor closely the compliance of manufacturers, importers, distributors, and retailers with this Act through surveillance inspections and investigations.

SEC. 14. *Penalties.* - The following penalties shall apply:

a. Violation of Sections 4 and 5, - On the first offense, a fine of not less than Two thousand pesos (PHP 2,000.00) but not more than Three thousand pesos (Php3,000.00).

On the second offense, a fine of not less than Three thousand pesos (PHP3,000.00) but not more than Five thousand pesos (Php5,000.00) shall be imposed.

On the third offense, in addition to a fine of Ten thousand pesos (Php10,000.00), the business permits and licenses to operate shall be cancelled or revoked.

b. Violation of Sections 6 and 7. - On the first offense, any person or any business entity or establishment selling to, distributing or purchasing ENDS/ENNDS or HTPs for a young person shall be fined the amount of not less than Five thousand pesos (Php5,000.00) or an imprisonment of not more than thirty (30) days, upon the discretion of the court. For succeeding offenses, both penalties shall apply in addition to the revocation of business licenses or permits in the case of a business entity or

establishment.

If the violation is by an establishment of business entity, the owner, president, manager, or the most senior officers thereof shall be held liable for the offense.

If a young person is caught selling, buying or using ENDS/ENNDS or HTPs, the provisions of Article 189 of Presidential Decree No. 603 otherwise known as The Child and Youth Welfare Code, as amended, shall apply.

c. Violation of Sections 8 to 12. - On the first offense, a fine of not more than One hundred thousand pesos (Php100,000.00) or imprisonment of not more than one (1) year, or both, at the discretion of the court shall be imposed.

On the second offense, a fine of Two hundred thousand pesos (Php200,000.00) or imprisonment of not more than two (2) years, or both, at the discretion of the court shall be imposed.

On the third offense, in addition to a fine of not more than Four hundred thousand pesos (Php400,000.00) or imprisonment of not more than three (3) years, or both, at the discretion of the court, the business permits and licenses, in the case of a business entity or establishment, shall be revoked or cancelled.

In the case of a business entity or establishment, the owner, president, manager or officials thereof shall be liable.

If the guilty officer is an alien, he shall summarily be deported after serving his sentence, and shall be forever barred from re-entering the Philippines.

SEC. 15. *Implementing Rules and Regulations.* - Within sixty (60) days from the approval of this Act, the Secretary of Health, in consultation and coordination with appropriate government agencies and other stakeholders, shall promulgate the necessary implementing rules and regulations for the effective implementation of this Act.

SEC. 16. *Separability Clause.* - If any provision of this Act is held invalid or declared unconstitutional, the other provisions which are not affected thereby shall remain valid and subsisting.

SEC. 17. *Repealing Clause.* - All laws, decrees, presidential proclamations, executive orders, rules and regulations or parts thereof inconsistent herewith, are hereby repealed or modified accordingly.

SEC. 18. *Effectivity.* - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,