

REPUBLIC OF THE PHILIPPINES
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
Third Regular Session

House Bill No. **8340**



Introduced by **MAGDALO Party-List Representative**
HON. GARY C. ALEJANO

EXPLANATORY NOTE

A Vaporized Nicotine Product Systems (VNPS) is a handheld electronic device that simulates the feeling of tobacco smoking. It works by heating a liquid to generate an aerosol, commonly called a "vapor", that the user inhales. Using VNPS is commonly referred to as vaping. The liquid in the e-cigarette, called e-liquid, or e-juice, is usually made of nicotine, propylene glycol, glycerine, and flavorings. Not all e-liquids contain nicotine.

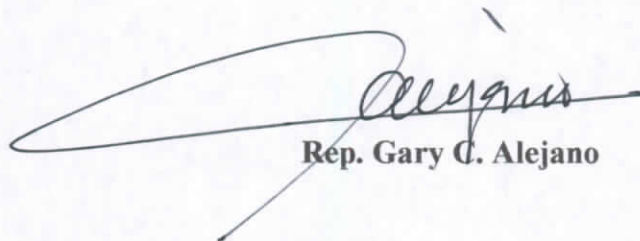
The health risks of Vaporized Nicotine Products are uncertain. They are likely safer than tobacco cigarettes, but are of unclear effect in relation to other methods of stopping smoking. Their long-term health effects are not known; they may help some smokers quit. When used by non-smokers, e-cigarettes can lead to nicotine addiction, and there is concern that children could start smoking after using e-cigarettes. So far, no serious adverse effects have been reported in trials. Less serious adverse effects include throat and mouth irritation, vomiting, nausea, and coughing.

VNPs create an aerosol, commonly called vapor and its exact composition varies. The majority of toxic chemicals found in tobacco smoke are absent in e-cigarette aerosol. Those present are mostly below 1% of the corresponding levels in tobacco smoke. The aerosol can contain toxicants and traces of heavy metals at levels permissible in inhalation medicines, and potentially harmful chemicals not found in tobacco smoke at concentrations permissible by workplace safety standards, however chemical concentrations may exceed the stricter public safety limits.

The lack of a regulatory scheme to oversee product standards and safety has also led to the placement of inferior quality products in the Philippine market. In fact, media reports of exploding VNP products are becoming increasingly common, with more than 200 reports of VNP-related explosions⁵ all over the world. These regrettable events could have been prevented had there been a proper regulatory scheme in place.

In response to this growing reality, this bill proposes that VNP products be regulated in such a way that any health claim is assessed by the Food and Drug Administration (FDA), registration and product quality and safety are in line with the standards set by the Department of Trade and Industry (DTI), sales and distribution to and from minors are prohibited, and both public and environmental health are protected.

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



Rep. Gary C. Alejano

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AN ACT
REGULATING VAPORIZED NICOTINE PRODUCTS

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

SECTION 1. Short Title.—This Act shall be known as the “**Vaporized Nicotine Products 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.

It is further declared the policy of the State to discourage the use of cigarette products and to look for effective measures in the fight against cigarette smoking by encouraging the availability of well-regulated, significantly less harmful alternatives to cigarettes for smokers who do not or cannot quit smoking.

SEC. 3. Definition of Terms.—For the purposes of this Act:

a. **Vaporized nicotine product** means a product with or without tobacco that generates a nicotine-containing aerosol without combustion, with or without electronics or any component of that product that includes but is not limited to a cartridge, a tank, and the device without the cartridge or the tank.

b. **Ingredients** mean any substance that is added to the tobacco or nicotine mixture and present in the finished product.

c. **Nicotine** means nicotinic alkaloids, including any salt or complex of nicotine whether derived from tobacco or synthetically produced.

1 d. **Nicotine mixture** means the nicotine-containing liquid, solid or other non-tobacco
2 substance in the product.

3 e. **Refill container** means a receptacle for holding nicotine mixture to refill certain
4 vaporized nicotine products.

5 f. **Emissions** means substances that are released when a product is consumed as intended,
6 such as substances found in cigarette smoke, or the aerosol generated by vaporized nicotine
7 products, or substances released during the process of using vaporized nicotine products.

8 g. **Harmful and Potentially Harmful Constituents (HPHCs)** shall refer to chemical
9 substances that pose potential health risks such as those identified by the World Health
10 Organization.

11 h. **Reduced exposure claim** means a communication to consumers in the product label or
12 marketing material that the product or its emissions contain a reduced level of, or are free of, a
13 substance or substances or present a reduced exposure to a substance or substances, such as
14 HPHCs.

15 i. **Reduced risk claim** means a communication to consumers in the product label or
16 marketing which represents explicitly that the product presents a lower risk or is less harmful than
17 continued cigarette smoking.

18 j. **Package** shall refer to bottles, boxes, cartons, or containers of any kind in which the
19 electronic equipment of a vaporized nicotine product is offered for sale to consumers.

20 k. **Nicotine receptacle** shall refer to bottles, boxes, cartons, or containers of any kind in
21 which a nicotine-containing solution or vaporized tobacco or any related product is offered for sale
22 to consumers for use with a vaporized nicotine product system.

23 l. **Point-of-sale** shall refer to any location at which an individual can purchase or otherwise
24 obtain vaporized nicotine products.

25 m. **Principal display surface** shall refer to the panel of the nicotine receptacle that faces the
26 consumer when displayed for sale.

27 n. **Advertising** shall refer to the business of conceptualizing, presenting, making available
28 and communicating to the public, through any form of mass media, any fact, data, or information

about the attributes, features, quality, or availability of consumer products, services, or credit. For the purpose of this Act, advertising shall be understood as vaporized nicotine product advertising.

SEC. 4. *Packaging Content.*—The packaging shall contain the following:

a. A list of all vaporized nicotine product device components; and

b. A leaflet or insert containing instructions for handling, proper use, and maintenance. It shall also include warnings against improper usage.

SEC. 5. *Health Warnings.*—Only nicotine receptacles shall bear textual health warnings with the following specifications:

a. Unit packets and any outside wrapping of vaporized nicotine product, nicotine receptacles such as e-juices, tobacco cartridges not intended for combustion, and similar products, shall carry the following health warning: “This product is addictive and may be harmful to your health.”

b. The health warning shall occupy 30% of the lower part of the principal display surface of the unit packet and any outside wrapping of the nicotine receptacle. The health warning shall occupy a total area of not less than fifty percent (50%) of the total warning frame.

c. Nothing shall be printed or applied on a location where it is likely to obscure or cover, in part or in whole, the health warning.

d. No part of the warning may be obliterated, obscured, folded, severed, or become unreadable when the nicotine receptacle is opened or closed or when a wrapper on the receptacle is removed.

Vaporized nicotine products shall not be covered by the Graphic Health Warnings Law.

SEC. 6. *Minimum Age Sales and Purchase.*—The following acts shall be prohibited:

a. The sale and distribution or transfer of vaporized nicotine products by any person to minors (anyone below 18 years old);

b. Purchasing, or otherwise receiving vaporized nicotine products from a minor; and

c. The sale, purchase, and use of vaporized nicotine products by minors.

1 It shall not be a defense for the person selling or distributing the vaporized nicotine
2 product/s that he/she did not know or was not aware of the real age of the minor. Neither shall it be
3 the defense that he/she did not know nor had any reason to believe that the product was for
4 consumption of the minor to whom it was sold.

5 **SEC. 7. Point-of-Sale Signage.**—Point-of-sale establishments offering, distributing, or
6 selling vaporized nicotine products to consumers shall post the following statement in a clear and
7 conspicuous manner. **“SALE/DISTRIBUTION TO OR PURCHASE BY MINORS OF**
8 **VAPORIZED NICOTINE PRODUCTS IS UNLAWFUL”** or **“IT IS UNLAWFUL FOR**
9 **VAPORIZED NICOTINE PRODUCTS TO BE SOLD/DISTRIBUTED TO OR**
10 **PURCHASED BY PERSONS UNDER 18 YEARS OF AGE.”**

11 **SEC. 8. Proof of Age Verification.**—Retailers shall ascertain that no individual purchasing a
12 vaporized nicotine product is below eighteen (18) years of age. In case of doubt, retailers shall
13 verify the age of the buyer through any valid identification card exhibiting the buyer’s photograph
14 and age or date of birth.

15 **SEC. 9. Advertisement Restrictions.**—Advertisements shall be allowed in points-of-sale,
16 through direct marketing, and on the internet. The following restrictions shall apply to all vaporized
17 nicotine product advertisements:

18 a. Advertisements shall not be aimed at or particularly appeal to persons under eighteen (18)
19 years of age;

20 b. Advertisements shall not contain cartoon characters or subjects that depict humans or
21 animals with comically exaggerated features or that attribute human or unnatural characteristics to
22 animals, plants or other objects;

23 c. Advertisements shall only depict persons who are or who appear to be above twenty- five
24 (25) years of age;

25 d. Advertisements shall not show, portray, or depict scenes where the actual use of, act of
26 using, or puffing of vaporized nicotine products;

27 e. Advertisements should not undermine quit-smoking messages and encourage non-tobacco
28 or nicotine users to use the product;

1 f. Advertisements do not contain any information or element that is untrue or not
2 scientifically substantiated, in particular with regards to product characteristics, health effects, risks,
3 or emissions;

4 g. Promotional communications shall allow for adult consumers to learn about the
5 availability of vaporized nicotine products, receive information about how to use them, try them
6 before purchasing them, subject to proof of age and certification of smoker status, and receive pre-
7 sale and after-sales support;

8 h. Advertisements shall not appear in television, radio, and cinema; and

9 i. All allowable advertisements and promotional materials for nicotine receptacles shall
10 contain the health warning: This product is addictive and may be dangerous to your health.” The
11 health warning shall occupy ten percent of the bottom area of the advertisement.

12 **SEC. 10. Restrictions on Advertisement in Print Media.**—Advertising and other promotional
13 communications of vaporized nicotine products shall be permitted so long as the publication is not
14 intended for minors and generally has an adult readership or subscriber base.

15 **SEC. 11. Public Place Use.**—Use of vaporized nicotine products indoor is prohibited in
16 places of worship, hospitals, or other healthcare centers, public conveyances, government offices,
17 and educational or recreational facilities exclusively intended for minors. In all other enclosed
18 spaces that are open to the general public, private workplaces, and those places not covered in the
19 preceding enumeration, vaporized nicotine product use shall be allowed, provided that the owner,
20 proprietor, operator, possessor, manager, or administrator of such places shall post the following
21 statement in a clear and conspicuous manner at every ingress point of such places: **“USE OF**
22 **VAPORIZED NICOTINE PRODUCTS IS ALLOWED INSIDE.”**

23 **SEC. 12. Product Standards and Assessments.**—Vaporized Nicotine Products must comply
24 with the following:

25 a. Vaporized nicotine products shall operate in such a way that no combustion of the
26 tobacco or nicotine mixture occurs during the entire process of consumption when used as intended;

27 b. All products must be manufactured in accordance with an appropriate quality
28 management system. The quality management system must ensure batch-to-batch reproducibility of
29 the products through quality control of both incoming materials and finished products; prevention

of mix-ups; and traceability from raw material supplier to distributor, with supporting documented evidence and a controlled change management process;

c. The substances listed below may not be added in vaporized nicotine products:

1. Additives that have carcinogenic, mutagenic, or reprotoxic properties in unburnt form;

2. Respiratory sensitizers;

3. Ethylene glycol;

4. Diethylene glycol;

5. Diacetyl; and

6. 2,3-pentanedione.

d. Manufacturers of electrical devices intended to be used in combination with a vaporized nicotine product shall ensure that such devices comply with applicable electrical safety standards; and

e. Batteries must comply with applicable industry requirements.

SEC. 13. *Tamper-proof and Child-proof Designs.*—All receptacles containing nicotine mixtures must be child-resistant, tamper-resistant, and protected against breakage and leakage.

SEC. 14. *Market Placing.*—Manufacturers and distributors must comply with the following:

a. Three (3) months prior to placing a vaporized nicotine product in the market, all manufacturers and importers must register their products with the Department of Trade and Industry (DTI) and submit information demonstrating compliance with product standards and assessment requirements;

b. Manufacturers or importers intending to present the product with any information about the product's health effects such as reduced exposure or reduced risk claims, must submit scientific evidence supporting such consumer communication to the Food and Drug Administration (FDA); and

c. For products that are already in-market, they shall be given three months to register their products with the DTI and submit information demonstrating compliance with product standards and assessment requirements. Any health claims for in-market products shall also be submitted to the FDA for approval.

SEC. 15. *Health Claims.*— Notwithstanding the foregoing provisions, there are only two (2) claims that vaporized nicotine product manufacturers and distributors may make:

a. Reduced exposure claim:

1. A reduced exposure claim may only be made if:

- A. The manufacturer characterizes the levels of nicotine uptake from vaporized nicotine products compared to cigarette smoking based on clinical trials;
- B. The manufacturer can support the claim with evidence from clinical trials conducted over a period of at least seven days demonstrating that, compared to continued cigarette smoking, users who switch completely to the product show a significant reduction in exposure to one or more HPHCs based on validated, scientifically-accepted biomarkers of exposure and that the reductions in exposure are significant enough that a reasonable scientific or medical expert would anticipate a reduction in risk of disease in smokers who switched to the product;
- C. The manufacturer demonstrates that the average user of tobacco product who is reasonably well-informed and reasonably observant and circumspect correctly comprehends the claim; and
- D. Clinical studies must be performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and be consistent with reasonable internationally accepted standards.

b. Reduced risk claim.

1. A reduced risk claim can only be made if:

- A. The manufacturer meets the requirements stipulated for reduced exposure claims;
- B. The manufacturer can support the claim with clinical studies; and

C. The manufacturer can support the claim with evidence from clinical trials conducted over a period of at least ninety days demonstrating that:

i. compared to continued cigarette smoking, users who switch completely to the product in conditions of actual use show a significant reduction in the level of each biomarker of exposure to HPHCs or that the reductions are within 20% of the reduction observed in smokers who quit cigarette smoking over the study period; and

ii. compared to continued cigarette smoking, users who switch completely to the product in conditions of actual use show a reduction in risk of harm or harm compared to continued smoking.

c. To characterize risk reduction in the absence of epidemiological evidence, a manufacturer may instead demonstrate favorable biological and physiological changes in chosen clinical risk endpoints as compared to continued smoking. These endpoints need to be effected by smoking, linked to smoking related disease and reversible after smoking cessation. The majority of the assessed clinical risk endpoints must shift in the direction of smoking cessation.

d. A reduced exposure or reduced risk claim is permissible only with regard to products for which adequate post-marketing surveillance is in place. The notification must include the plans for such post-marketing surveillance and studies to determine the impact of the marketing of the product on the population.

Products substantiated as *reduced exposure* or *reduced risk* pursuant to this Section may make such claims on product packaging and nicotine receptacles.

The FDA shall be the responsible authority with respect to claims of reduced exposure or reduced risk.

SEC. 16. Penalties for Non-Compliance.—The following penalties shall individually apply to manufacturers, importers, distributors, and sellers of vaporized nicotine products as well as their agents/representatives for any violation of this Act:

a. On the first offense, a fine of not more than One Hundred Thousand Pesos (P100,000.00).

b. On the second offense, a fine of not more than Five Hundred Thousand Pesos (P500,000.00).

1 c. On the third offense, a fine of not more than One million pesos (P1,000,000.00) or
2 imprisonment of not more than five (5) years, or both, at the discretion of the court: *Provided, That*
3 the business permits and licenses, in the case of a business entity or establishment shall be revoked
4 or cancelled.

5 Non-compliant vaporized nicotine products found in the market for sale or distribution shall
6 be subject to confiscation.

7 If the guilty officer is a foreign national, he shall be deported after service of sentence and/or
8 payment of applicable fines without need of further deportation proceedings and shall be
9 permanently barred from re-entering the Philippines.

10 **SEC. 17. *Creation of a Congressional Oversight Committee.***—A congressional oversight
11 committee co-chaired by the Senate Committees on Trade, Commerce, and Entrepreneurship and
12 Health and Demography and the House Committees on Trade and Health, is hereby constituted to
13 monitor and review the implementation of this Act.

14 **SEC. 18. *Implementing Rules and Regulations.***—The DENR, DOT, DOTr, DPWH, DOH,
15 DILG shall promulgate the implementing rules and regulations of this Act within ninety (90) days
16 from its effectivity.

17 **SEC. 19. *Repealing Clause.***—All laws, decrees, executive orders or parts thereof
18 inconsistent with the provisions of this Act is hereby repealed or modified accordingly.

19 **SEC. 20. *Separability Clause.***—If any part or provision of this Act is declared invalid or
20 unconstitutional, the other parts not otherwise affected shall remain in full effect and force.

21 **SEC. 21. *Effectivity.***—This Act shall take effect fifteen days after its complete publication
22 in at least two newspapers of general publication.

Approved,