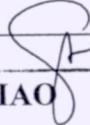


EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)

Senate Bill No. 556
Office of the Secretary

SENATE
S.B. No. 556

19 JUL 16 P 2:46

RECEIVED BY 

INTRODUCED BY: SENATOR EMMANUEL D. PACQUIAO

AN ACT

EMPOWERING THE PHILIPPINE INSTITUTE OF TRADITIONAL AND
COMPLEMENTARY HEALTH CARE BY VESTING UPON IT REGULATORY
POWERS, PROVIDING IT WITH AUGMENTED HUMAN RESOURCES AND
UPGRADED EQUIPMENT, ESTABLISHING TESTING LABORATORIES AND
FIELD OFFICES, AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO.
8423 AND APPROPRIATING FUNDS THEREOF

EXPLANATORY NOTE

In 1992, the government formally recognized the vital role of traditional medicine in the country and launched the Traditional Medicine Program under the leadership of former Health Sec. Juan Flavier. In 1997, the Congress enacted RA No. 8423, otherwise known as the Traditional and Alternative Medicine Act (TAMA) of 1997, which created the Philippine Institute of Traditional and Alternative Health Care (PITAHC). PITAHC, a government-owned and controlled corporation (GOCC) attached to the Department of Health (DOH), was primarily envisioned to help improve the quality and delivery of health care services to the Filipino people through the development of traditional and alternative health care (TAHC) and its integration into the national health care delivery system.

With the passage of time, there is a need to revisit the said law and confer more power to the PITAHC to provide better service to the people. There is a need to amend the current law to institutionalize added measures that will endure the safety of practice and encourage consumers to obtain alternative health care services only from qualified practitioners.

This bill seeks to strengthen the PITAHC and grant it with more regulatory powers to provide better administrative and technical assistance to the people. It primarily endeavors to enhance the administrative and technical capacity of PITAHC by upgrading its equipment, establishing its own testing laboratories and field offices and augmenting its human resources. Moreover, this Act also aims to deliver a wider range of health products and practices that are guaranteed to be safe and effective.

This legislation is deemed necessary especially in rural areas where traditional and complementary medicine (T&CM) are sometimes the only affordable and available source of health care.

Thus, the immediate passage of this measure is earnestly sought.



EMMANUEL D. PACQUIAO

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OFFICES, AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 8423 AND
APPROPRIATING FUNDS THEREFOR

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

CHAPTER I

Title

Section 1. *Short Title* – The Philippine Institute of Traditional and Alternative Health Care (PITAHC) is hereby renamed to Philippine Institute of Traditional and Complementary Health Care. Thus, this Act shall be known as the **“Philippine Institute of Traditional and Complementary Health Care (PITCHC) Act of 2019.”**

CHAPTER II

Objectives

Section 2. *Objectives* – This Act aims to strengthen the Traditional and Complementary Health Care System in the country to provide the people with wider range of health products and services that are proven to be safe, efficient, effective and of quality at much affordable prices.

CHAPTER III

Police and Regulatory Powers

Section 3. *Transfer to and vesting upon PITCHC Police and Regulatory Powers* – Without any intention to trivialize the regulatory capacity of the Food and Drug Administration, the necessary

1 police and regulatory powers over the Traditional and Complementary Health Care Industry are
2 hereby transferred from the FDA and vested upon PITCHC to fully empower the latter to
3 effectively discharge its mandate under the law.

4

5 **Section 4. Regulatory Functions** – No traditional and complementary health care practice,
6 service or business shall be allowed unless duly certified or authorized. No traditional and
7 complementary health care product, device or modality shall be sold, dealt with or made
8 available to the public unless duly registered, approved and certified, all by the PITCHC.

9

10 Thus, to carry out this mandate and all the other provisions of this Act, the PITCHC shall have
11 the following functions and powers, in addition to those already stated in Section 6 of RA 8423:

12

13 a)To prescribe the necessary guidelines, criteria and requirements to be complied
14 with in the registration of new health products, devices or modalities;

15

16 b)To establish health product standards of identity, purity, safety, efficacy and
17 quality based on validated and accepted analytical data;

18

19 c)To assume primary authority to inspect, collect and analyze samples of all health
20 products covered by this Act;

21

22 d)As a condition for registration, approval and certification, to require and conduct
23 appropriate tests on all health products that are intended to be made available to the
public to ensure safety, efficacy, purity and quality.

24

25 e)To prescribe guidelines and criteria which shall serve as basis for its
26 evaluation and determination of adulterated and misbranded/mislabeled health
27 products and for the proper handling or disposal of the same.

28

29 f)To issue certificates of compliance or grants of authority to manufacturers,
30 importers, exporters, distributors, wholesalers, drug outlets and other establishments
31 and facilities of health products after spot-check and/or after their due compliance
32 with technical and regulatory requirements. These certificates or grants shall serve as
33 license of the covered entities to operate and/or to continue operating.

34

35 g) To establish a training center for trainers using its existing resources and facilities.
36 The training center shall serve as demonstration area and venue for the
37 conduct of continuing health care education for professors, consultants and trainers,
38 who themselves must be PITAHC accredited, involved in the art and science of
39 alternative health care throughout the country.

40

41 h) To accredit or certify schools or training centers that are seeking to offer
42 standardized traditional and alternative health care education or programs and to hold

1 relevant trainings after their due compliance with technical and other regulatory
2 requirements.

3
4 i) To issue license or authority to practice T&CM to qualified applicants after passing
5 the required standard examinations to be conducted after their due compliance with
6 the required relevant instructions and training programs taken only from such
7 PITAHC-accredited or established traditional and alternative health care schools or
8 training centers. The standard examination shall be required to all persons
9 seeking to practice T&CM except those who are expressly exempted by this Act.
10

11 j) To require practitioners, as a condition for the annual renewal of their certificates
12 or grants of authority to practice, to undergo mandatory continuous learning
13 programs and trainings relevant to their field.
14

15 k) To accredit, after due compliance with all the appropriate guidelines and
16 requirements, centers that are seeking to offer T&CM services.
17

18 l) To approve, after establishing the necessary guidelines and criteria, traditional and
19 alternative health care modalities that can only be availed of by the public.
20 Modalities that may be newly introduced in the Philippines shall only be approved
21 after the necessary study, evaluation and tests to ensure its safeness and efficacy.
22

23 m) To require foreign or Filipino practitioners who have been certified by foreign
24 jurisdictions to undergo the required examination provided for under paragraph
25 (i) of this Section and to show proofs of the programs and trainings they have
26 undertaken from and the authority of the certifying body in such foreign jurisdiction
27 before granting them the authority to practice in the Philippines. Further, should they
28 qualify, their practice shall only be limited to such modalities that are already
29 approved by the PITAHC. Should they intend to introduce a modality that is not yet
30 PITAHC-approved, paragraph (l) of this Section, in addition to herein requirements,
31 shall apply.
32

33 n) To exercise visitorial power and the power to inspect over all traditional and
34 alternative health care establishments, buildings, facilities, centers and schools to
35 ensure compliance with the provisions of this Act and such other applicable laws.
36

37 o) To issue cease and desist orders, *motu proprio* or upon a verified complaint, to
38 covered entities and facilities in case of an identified or reported violation of or
39 grievance arising from entities, products or services covered by this Act.
40

41 p) After observance of due process, to order the ban, recall, and/or withdrawal of any
42 T&CM product; or the cancellation or revocation of certificates or authorizations

granted to an entity or practitioner covered by this Act in case of death, serious illness or injury of a consumer/client or if it be found that such T&CM product, service or entity is imminently injurious, unsafe, dangerous or grossly deceptive.

q) To levy, assess, and collect fees for analysis and testing of T&CM products and inspection of all entities covered by this Act.

r) To maintain a surveillance system to continuously monitor and regulate the traditional and alternative health care industry.

s) To conduct an independent investigation on and maintain records of health and safety issues arising from the traditional and alternative health care industry.

t) To initiate appropriate legal actions, whenever necessary or applicable, against any person found to be violating any of the provisions of this Act.

u) To prescribe standards and guidelines on and regulate information dissemination, advertisements and promotions, and other marketing activities regarding T&CM products, services and devices.

v) To establish and maintain a bonded warehouse/s, whenever necessary or appropriate, as determined by the director-general to be used as storage for confiscated T&CM products unless the same are deemed to be destroyed.

w) To exercise such other powers and perform such other functions as may be necessary to carry out its duties under this Act.

Chapter IV

Special Rules and Exemptions

Section 5. Traditional Medicine Practitioners – Recognizing the unique manner of obtaining the knowledge and skills of traditional medicine, it being handed down from one generation to another without the influence of formal education or training, practitioners belonging to this category shall be exempt from the standard examination required by this Act. Nonetheless, they are still mandated to acquire the necessary grant of authority in accordance with the guidelines to be prescribed by PITCHC. It shall be necessary for traditional practitioners to establish the length of time for which they have been known to have practiced Traditional Medicine and prove that, in the course of their practice, no related complaint, whether reported or not, was made against them.

Further, should they dispense, whether for a fee or not, or use as a modality traditional health products, practitioners must seek for the approval of the same.

Section 6. Practitioners with Disability/Blind Masseurs – Persons with disability or visually-impaired persons seeking to offer T&CM services shall likewise be exempt from the standard examination required by this Act. Nonetheless, they shall be required to obtain the necessary certification from PITCHC after due compliance with the necessary instructions and trainings from accredited training schools or centers under the guidance of or in coordination with the National Council on Disability Affairs, TESDA/DepEd/CCHED, and other relevant government agencies.

CHAPTER V

Prohibited Acts and Penalties

In view of its applicability over the traditional and complementary health care industry, the following prohibited acts and penalties provided for under Republic Act 9711, otherwise known as the Food and Drug Administration Act of 2009, and Republic Act 3720, otherwise known as Food, Drug and Cosmetic Act, are hereby faithfully adopted except for some modifications to make the provisions more in keeping with the rest of this Act:

Section 7. Prohibited Acts

A. Health Products

- a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of any health product that is adulterated, unapproved, unregistered or misbranded.
 - b) The adulteration or misbranding of any health product.
 - c) Refusal to permit entry or inspection as authorized by paragraphs (k) and (o) of Section 4 hereof or to allow samples to be collected.
 - d) The giving of a guaranty or undertaking referred to in the second paragraph of Section 8 (A)(b) hereof which guaranty or undertaking is false except by a person who relied upon a guaranty or undertaking to the same effect, signed by, and containing the name and address of the person or entity from whom he received in good faith the health products or the giving of a guaranty or undertaking referred to in Section 10 (b) which guaranty or undertaking is false.
 - e) Forging, counterfeiting, simulating or falsely representing or ,without proper authority, using any mark, stamp, tag, label or other identification devise authorized or required by regulations promulgated under the provisions of this Act.
 - f) The use by any person for his own advantage, or revealing other than to the Secretary or officers or employees of the Department o Health or to the courts

- when relevant in any judicial proceeding under this Act any information acquired by virtue of the PITCHC's exercise of its visitorial power or power to inspect.
- g) The alteration, mutilation,, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to health products of such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded Provided, a retailer may sell in smaller quantities subject to guidelines issued by the PITCHC.
 - h) The use, on the labeling of any health product or in any advertisement relating to the same, of any false or misleading representation or suggestion with respect to the registration of such product.
 - i) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement, or sponsorship of any health product which, although requiring registration, is not registered with the PITCHC pursuant to this Act.
 - j) The sale, offering for sale, importation, exportation, distribution or transfer of any health product beyond its expiration or expiry date, if applicable.
 - k) The act of intentionally committing fraud and misrepresentation or use of falsified or forged documents in obtaining the necessary PITCHC approval or certificate or grant of authority. This is without prejudice to the exercise of PITCHC of its power to revoke or cancel certificates, grants or approval it has issued.

B. Traditional and Complementary Health Care (TaCHC) Services

- a) The practice of any of the approved TaCHC modalities by any person or TaCHC center without the appropriate license or grant of authority to practice.
- b) The continuous practice of any of the approved TaCHC modalities by any practitioner or TaCHC center whose accreditation or grant of authority has already expired or has been cancelled or revoked.
- c) The practice of any unapproved TAHC modalities by any person, whether certified or not to practice in the Philippines.
- d) The mere act of introducing to the public by any person, certified or not, of a TAHC modality that is not validly approved by PITCHC.
- e) The act of a certified practitioner of allowing a person to commit an unauthorized practice of TaCHC whether it be under his direct or indirect supervision.
- f) The act of assisting in an unauthorized practice of TaCHC, whether for profit or not.
- g) The act of using traditional and alternative health products and services to cause injury, illness or death to a consumer or customer.
- h) Offering TaCHC programs and trainings or rendering TAHC services by schools or training centers without the appropriate certification or approval of PITCHC.
- i) Rendering taCHC services by accredited schools or training centers that are beyond the scope of their approved programs and training.

- j) The act of committing fraud and misrepresentation or use of falsified or forged documents in obtaining the necessary PITCHC approval or certificate or grant of authority.
 - k) The refusal to permit entry or inspection as authorized by paragraphs (k) and (o) of Section 4 hereof.

any other act which violate or undermine any of the explicit powers of or which tends to impede the PITCHC from exercising any of its functions provided for in this Act.

Section 8. *Penalties*

A. For Health Products

- a) Any person who violates any of the provisions of paragraph A of Section 7 hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (Php 50,000.00) but not more than Five hundred thousand pesos (Php 500,000.00), or both, at the discretion of the court: Provided, that if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (Php 500,000.00) shall be imposed: Provided, further, that an additional fine of one percent (1%) of the economic value/cost of the violative product, or One thousand pesos (Php 1,000.00), whichever is higher, shall be imposed for each day of continuing violation: Provided, finally, that health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the PITAHC that such health products may cause injury or prejudice to the consuming public.
 - b) No person shall be subject to the penalties of subsection (a) of this section (1) for having sold, offered for sale or transferred any article and delivered it, if such delivery was made in good faith, unless he refuses to furnish on request of PITCHC's authorized inspectors or duly designated officer or employee, the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; (2) for having violated Section 7-A (a) if he established a guaranty or undertaking signed by, and containing the name and address of, the person residing in the Philippines from whom he received in good faith the article.

B. For acts prohibited under Section 7 (B) and (C)

1
2 Any person who violates any of the provisions of paragraph (B) and (C) of Section 7
3 hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1)
4 year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (Php
5 50,000.00) but not more than Five hundred thousand pesos (Php 500,000.00), or both, at
6 the discretion of the court.

7
8 The imposition of penalties under both paragraphs (A) and (B) of this section shall be
9 without prejudice to the issuance of cease and desist order or to the exercise of PITCHC
10 of its power to revoke or cancel certificates, approvals or grants it has issued and/or to the
11 filing of appropriate civil or criminal action, whenever appropriate or necessary.

12
13 In case of illness, injury or death as provided for under paragraph (f) of Section 7, the
14 intentional use of traditional or complementary health care product/service shall not
15 constitute a separate crime. Rather, the use or employment of such product or service
16 shall serve as an aggravating circumstance as provided for by the Revised Penal Code.
17

18 Should the offense be committed by a juridical person, the Chairman of the Board of
19 Directors, the president, general manager, or the partners and/or the persons directly
20 responsible therefore shall be penalized.

21
22 Should the offense be committed by a foreign national, he/she shall, in addition to the
23 penalties prescribed, be deported without further proceedings after service of sentence.
24
25

26 CHAPTER VI 27 The Executive and Officers of the Institute 28

29 **Section 9.** Section 9 of RA 8423 is hereby amended to read as follows:

30
31 **Sec. 9. (a) Director General** The Institute shall be headed by a Director General who
32 shall be appointed by the President of the Philippines upon the recommendation of the
33 Secretary of Health for a term of six (6) years. The Director General shall enjoy the
34 benefits, privileges and emoluments equivalent to the rank of Undersecretary.
35

36 As Chief Executive Officer of the Institute, the Director general shall exercise general
37 supervision and control over the operations of the Institute save those affairs that are
38 exclusively within the function of the Board.

39
40 **(b) Deputy Director General.** The Director general shall be assisted by two (2) Deputy
41 Director General(s), one for administration and finance and another for field regulatory
42 operations. The Deputy Directors shall be career official(s) and shall enjoy the benefits,

privileges and emoluments equivalent to the rank of an Assistant Secretary.

(c) Other Officers. The Director General shall likewise be assisted by directors, department managers/coordinators and such other officers as the Board may authorize. The position, titles, ranks and emoluments of such officers shall be determined by the Board.

Section 10. Transfer of Power from the Board to the Director General – The power to appoint, transfer, promote, suspend, remove or otherwise discipline any subordinate officer or employee of the Institute shall be transferred from the Board and be vested upon the Director General, thereby, effectively amending Sections 8 and 10 of RA 8423.

CHAPTER VII

PITCHC Centers and Offices

Section 11. To Facilitate the conduct of business and the discharge of its responsibilities, the PITCHC shall have the following centers and offices:

- a) Three major centers shall be established, namely:

 - i. Center for Regulation and Research of T&CM Product and Device
 - ii. Center for Regulation of T&CM Practice which may be subdivided further into two sections: one, for modalities and one, for practitioners
 - iii. Center for Regulation of T&CM Training Centers

er shall be headed by a Director. The Center for Health Product Regulation and Research at least three divisions: (1) licensing and registration division, (2) product research and ent division, and (3) laboratory support division the two other centers shall have at least ons: (1) Authorizing/Certifying Division and (2) Research and Development Division.

 - b) The Administration and Finance Office to be headed by the deputy director-general for administration and finance. It shall consist of the Human Resource Division, Property and Logistics Management Division, Assets and Financial Management Division, and the Information and Communication Technology Management Division.
 - c) The Field Regulatory Operations Office to be headed by the deputy director-general for filed regulatory operations.

- 1 d) The Policy and Planning Office which shall include a training, advocacy and
2 communications division shall be responsible for the performance monitoring of
3 the product research and development enters.
4 e) The Legal Services Support Center which shall provide legal services to and for the
5 entire PITAHC.

6

7

8 **CHAPTER VIII**

9 **Testing Laboratories and Field Offices**

10

11 **Section 12. Testing Laboratories** – There shall be established, in addition to the main laboratory
12 at the central office, at least one testing laboratory strategically located in Luzon, Visayas and
13 Mindanao. These laboratories shall be equipped with the necessary and appropriate equipment
14 and personnel complement.

15

16 **Section 13 Field Offices** – There shall be established field/satellite offices upon which
17 appropriate powers and functions of the PITCHC may be devolved upon. These offices shall be
18 mainly comprised of administrative, licensing, inspection and compliance divisions.

19

20

21 **CHAPTER IX**

22 **Human Resource**

23

24 **Section 14.** The PITCHC shall review its staffing pattern, positions and titles. New or additional
25 positions, titles or ranks shall be created if there be a need for additional manpower as identified
26 and determined by the Director General and approved by the Board.

27

28 **Section 15. Transfer of personnel from the Food and Drug Administration** – Personnel of the FDA
29 who are charged with function relative to traditional and complementary health products and who
30 may be disadvantaged by the implementation of this Act shall be transferred to PITCHC without
31 any loss of any benefit, incentives or seniority rights that are already existing at the time of the
32 implementation of this Act.

33

34

35 **CHAPTER X**

36 **Retention of Income**

37

38 PITCHC shall have the right to retain all of its income derived from the operations of the Herbal
39 Pharmaceutical and Processing Plants and its other income generating services/activities and
40 shall be utilized to augment its needed maintenance and operating expenses, capital outlays,
41 upgrading and modernization.

1
2 **CHAPTER XI**
3 **Miscellaneous Provisions**
4

5 **Section 16.** *Appropriation* – The amount necessary for the implementation of this Act shall be
6 charged against the current appropriations of the Philippine Institute of Traditional and
7 Alternative Health Care. The appropriation may be augmented by the income which the PITCHC
8 is authorized to retain and use under this Act. Thereafter, such amount as may be necessary for
9 the continued operation of the PITCHC shall be included in the annual General Appropriations
10 Act.

11
12 **Section 17.** *Implementing Rules and Regulations* – The DOH, in consultation with the PITCHC,
13 shall promulgate the implementing rules and regulations of this Act within one hundred twenty
14 (120) days following the passage of this Act.

15
16 **Section 18.** *Separability Clause* – If, for any reason or reasons, any part of the provision of this
17 Act shall be held to be unconstitutional or invalid, other parts or provisions hereof which are not
18 affected thereby shall continue to be in full force and effect.

19
20 **Section 19.** *Repealing Clause* – All laws, decrees, executive orders and issuances, ordinances,
21 rules and regulations or parts thereof inconsistent with the provisions of this Act are hereby
22 repealed or modified accordingly.

23
24 **Section 20.** *Effectivity* – This Act shall take effect fifteen (15) days after its publication in the
25 Official Gazette or in at least two (2) national newspapers of general circulation. The publication
26 shall not be later than seven (7) days after the approval hereof.

27
28
29
30 *Approved,*