#### REPUBLIC OF THE PHILIPPINES HOUSE OF REPRESENTATIVES QUEZON CITY

EIGHTEENTH CONGRESS First Regular Session



HOUSE BILL NO.

Introduced by REPRESENTATIVES ENRICO A. PINEDA and MICHAEL ODYLON L. ROMERO, PhD.

2486

#### **EXPLANATORY NOTE**

Section 2, Paragraph 2 of Republic Act No. 9165, otherwise known as the Dangerous Drugs Act of 2002, provided that "the government shall however aim to achieve a balance in the national drug control program so that people with legitimate medical needs are not prevented from being treated with adequate amounts of appropriate medications, which include the use of dangerous drugs."

This bill seeks for the use of cannabis for medicinal purposes. For more than 5,000 years, people have been using cannabis as a substance for relieving various ailments. It was used extensively as a cure for severe pain, as an anti-pyretic to reduce high fever, a sleeping aid to people with insomnia, administered as a relaxant to those with involuntary muscle spasms or seizures and as a salve to treat gastro-intestinal disorders, among other things.

Recently, cannabis, popularly known as marijuana, is being prescribed for the treatment of people with epilepsy where it is proven to be effective in quelling severe seizures, especially in children. It has also been given to patients afflicted with cancer because of its ability to reduce the painful symptoms of the disease, while providing relief from the nausea and vomiting associated with chemotherapy. It remains an effective analgesic, able to relieve severe neurological and muscular pain. Likewise, it is prescribed for the relief of rheumatoid-arthritis.

The use of medicinal marijuana has, as of 2017, been made legal in more than half of the territory of the United States of America. Worldwide, there are now more than 30 countries that have legalized the use of medicinal marijuana. While other countries legalized cannabis even for recreational uses, this measure only seeks to provide our countrymen an additional treatment option where conventional methods are found ineffective, while providing for control measures and strict regulation of its use. The intention of this bill is in consonance with Section 11 of the Constitution which provides that "it is the policy of the State to adopt an integrated and comprehensive approach to health

development which shall endeavor to make essential goods health and other social services available to all the people at affordable cost."

This bill was filed in the  $17^{th}$  Congress, underwent thorough deliberations and was subsequently passed on the Third Reading. Hence, immediate passage of this measure is earnestly prayed for.

ENRICO A. PINEDA 1PACMAN

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## Introduced by REPRESENTATIVES ENRICO A. PINEDA and MICHAEL ODYLON L. ROMERO, PhD.

# AN ACT PROVIDING COMPASSIONATE AND RIGHT OF ACCESS TO MEDICAL CANNABIS AND EXPANDING RESEARCH INTO ITS MEDICINAL PROPERTIES

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 "Philippine Compassionate Medical Cannabis Act".

**SECTION 2. Declaration of Policy.** – Pursuant to Section 11, Article XIII of the 1987 Constitution, it shall be the policy of the State to adopt an integrated and comprehensive approach to health development which shall endeavour to make essential goods, health and other social services available to all the people at affordable cost. The State shall protect and promote the right to health of the people and instill health consciousness among them.

Furthermore, in accordance with Section 2 of Republic Act No. 9165 or the Comprehensive Dangerous Drugs Act, as amended, the State shall provide measures to achieve balance in the national drug control program so that patients with debilitating medical condition may receive adequate amount of treatment and appropriate medications from the regulated use of dangerous drugs.

Finally, Section 2 of Republic Act No. 8423 or the Traditional and Alternative Medicine Act (TAMA) of 1997 provides that it shall be the policy of the State to improve quality and delivery of health care services to the Filipino people through the development of traditional and alternative health care and its integration into the national health care delivery system. It also provides that the State shall seek a legally workable basis by which indigenous societies would own their knowledge of traditional medicine.

Towards this end, the State shall legalize and regulate the medical use of cannabis which has been confirmed to have beneficial the therapeutic uses to treat a chronic or debilitating disease or medical condition that produces one or more of the following: cachexia or wasting syndrome; severe and chronic pain; severe nausea; seizures, including those characteristic of epilepsy; or severe and persistent muscle spasms, including those associated with multiple sclerosis.

### SECTION 3. Definition of Terms. - As used in this Act:

- a.) Cannabis refers to every kind, class, genus, specie of the plant Cannabis sativa L., Cannabis Americana, hashish, bhang, guaza, churrus, ganjab and embraces every kind, class and character of marijuana, whether dried or fresh and flowering or fruiting tops, or any part or portion of the plant and seeds thereof, and all its geographic varieties, whether as a reefer, resin, extract, tincture or in any form whatsoever;
- b.) Compassionate refers to a virtue combining concepts such as sympathy, empathy, fellow feeling, benevolence, care, love, and sometimes pity and mercy. A profound awareness of another's suffering coupled with a desire to alleviate that suffering.
- c.) Debilitating medical condition refers to any disease that produces one or more of the following: cachexia or wasting syndrome; severe and chronic pain; severe nausea; seizures, including those associated with multiple sclerosis. Debilitating medical conditions include the following diseases: 1) cancer; 2) glaucoma; 3.) multiple sclerosis; 4) damage to nervous system of the spinal cord, with object neurological indication of intractable spasticity; 5) epilepsy; 6) positive status for human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS); 7) post-traumatic stress disorder; 8) rheumatoid arthritis or similar chronic autoimmune inflammatory disorders; 9) diseases requiring admission into hospice care; and 10) any other debilitating medical condition or its treatment that is subsequently identified by the Department of Health as recommended by a panel of doctors constituted for this purpose.
- d.) Medical Cannabis Compassionate Center (MCCC) refers to any entity duly registered and licensed by the Department of Health (DOH) to acquire, possess, deliver, transfer, transport, sell, supply and dispense cannabis, devices or related supplies and educational materials to duly registered qualified patients.
- e.) Medical Cannabis Research and Safety Compliance Facility (MCRSCF) refers to any entity registered with the DOH that conducts scientific and medical research on medical use of cannabis and provides testing services for its potency and contaminants relative to its safe and efficient use, cultivation, harvesting, packaging, labelling, distribution and proper security.
- f.) Medical Cannabis refers to the use of cannabis including its constituents, tetrahydrocannabinol (THC), and other cannabinoids, as a physicianrecommended form of medicine or herbal therapy. Medical cannabis shall not be used in its raw form.
- g.) Medical use refers to delivery, possession, transfer, transportation, or use of cannabis and its devices to treat or alleviate a registered qualified patient's medical condition or symptoms associated with the patient's debilitating disease or its acquisition, administration, cultivation, or manufacturing for medical purposes.

**SECTION 4. Regulatory Agencies.** – The following shall be the regulatory agencies for this Act:

- a) Department of Health (DOH). The DOH, in consultation with the Food and Drug Administration (FDA), shall be the principal regulatory agency for the use of medical cannabis. It shall register and issue licenses to qualified entities engaged in activities related to the use of medical cannabis. The DOH shall maintain a registry of cannabis patients and their caregivers.
- b) Philippine Drug Enforcement Agency (PDEA). The PDEA shall have a key role in monitoring and regulating the dispensation of medical cannabis in health facilities. It shall maintain a registry of qualified medical cannabis physicians and caregivers licensed to prescribe and administer medical cannabis to qualified patients under this Act.

**SECTION 5.** Advisory Committee on Medical Use of Cannabis. - The is hereby established in the DOH an Advisory Committee on the Medical Use of Cannabis, hereinafter referred to as the Advisory Committee, which shall assist and provide directions in the formulation and implementation of the policies and regulations covered under this Act. The Directors-General of the FDA and the PDEA or their representatives shall be permanent members of the Advisory Committee.

The Secretary shall appoint the other members of the Advisory Committee which shall include health care practitioners, patients or representatives of patients with debilitating conditions, experts in the regulation of controlled substances for medical use, medical cannabis industry professionals and law enforcement agencies.

The Secretary shall form a Subcommittee of the Advisory Committee to advise the Secretary on clinical matters relating to medical cannabis, the members of which shall predominantly be clinical professionals in appropriate areas of expertise and shall also include representatives of patients. Members of the Subcommittee need not be members of the Advisory Committee. Both members of the Advisory Committee, and Subcommittee shall serve at the pleasure of the Secretary and may receive honoraria in accordance with existing government rules and regulations.

**SECTION 6. Qualified Medical Cannabis Physician.** – To be considered competent to certify a patient's medical need to use cannabis for treatment and to prescribe such treatment, a physician shall possess the following qualifications:

- a) has an established bona fide relationship with the patient:
- b) is licensed by the PDEA to prescribe medical cannabis to qualified medical cannabis patients; and
- c) professional knowledge of the use of medical cannabis

**SECTION 7. Qualified Medical Cannabis Patient.** – A qualified medical cannabis patient means a person who has been diagnosed by a certifying physician with bona fide relationship with the patient as having a debilitating medical condition as defined in Section 3 (c) and who, in the physician's professional evaluation, should receive therapeutic or palliative benefits from the medical use of cannabis.

The patient shall have the right to choose the type of medicine and health care services needed to alleviate the medical condition.

**SECTION 8. Identification Cards.** - The Secretary shall issue identification (ID) cards to the following:

- a) A registered qualified patient who complies with the DOH documentary requirements and the provisions of this Act; and
- b) Qualified caregivers as identified in Section 9 of this Act.

If the qualified patient is younger than eighteen (18) years of age, the certifying physician is mandated to explain to the patient as well as to the custodial parent or legal guardian who has responsibility to make health care decisions on behalf of the qualified patient the potential risks and benefits of the medical use of marijuana.

The custodial parent or legal guardian shall signify, in writing, their consent to the following:

- 1. Allow the qualified patient's medical use of cannabis;
- 2. Serve as the qualified patient's designated caregiver; and
- 3. Regulate the acquisition, dosage, and frequency of medical use of cannabis by the patient.

**SECTION 9. Medical Cannabis Patient Caregiver.** – The qualified patient's designated caregiver as identified in Section 8 of this Act shall be licensed by PDEA to administer dangerous drugs. A cannabis patient caregiver not covered by Section 8 of this Act must be at least twenty-one (21) years of age, and as far as practicable, a registered nurse duly licensed by PDEA, and must not have been convicted of an offense for the use of dangerous drugs under Republic Act No. 9165 or the Comprehensive Dangerous Drugs Act as amended. The caregiver shall give consent in writing to perform the following:

- a) Assist the qualified patient in the medical use of cannabis,
- b) Not divert the medical cannabis in one's possession to any person other than the patient, and
- c) Assist only one (1) cannabis patient at a time.

Convicted drug pushers, importers, illegal cultivators and manufacturers, and processors shall be disqualified as caregivers.

**SECTION 10. Medical Cannabis Compassionate Center (MCCC).** – An entity shall operate as a Medical Cannabis Compassionate Center after the approval of its application and license to operate with the DOH – Health Facilities and Services Regulatory Bureau (DOH-HFSRB). The Secretary shall establish a system for the evaluation of application

and licensing of a Medical Cannabis Compassionate Center based on the following criteria:

- The suitability of the applicant's proposed location including compliance with any local zoning laws and the geographic convenience to patients;
- b) The qualification, character and relevant experience of principal officer and board members, including any training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, or cannabis cultivation and preparation, and their experiences in running a health or medical center;
- c) The applicant's effective and efficient system of operations and services, including its staffing and training plans, the sufficiency of its capital to operate, and its ability to provide an adequate and affordable supply of medical cannabis to registered patients;
- d) The sufficiency of the applicant's procedure for accurate record keeping;
- The sufficiency of the applicant's measures for safety, security, and the prevention of diversion, including proposed locations and security devices to be employed;
- f) The applicant's procedure for safe and accurate packaging and labelling of medical cannabis, including the measures to ensure that all medical cannabis shall be free from contaminants; and
- g) The applicant's assurance that medical cannabis products being used are organic, pesticide-free, and gluten-free, and that no chemicals have been used in the extraction process as certified by the Food and Drug Administration.

**SECTION 11.** Access to Medical Cannabis. – Cannabis shall only be accessed through the following health facilities:

- a) DOH-retained hospitals,
- b) Specialty hospitals, and
- c) Private tertiary hospitals duly licensed and registered with the DOH for this purpose.

An MCC shall be authorized by the abovementioned hospitals to dispense medical cannabis within the hospital's premises.

An MCC shall guarantee the appropriate dispensation of cannabis through a pharmacist with an S3 license issued by the PDEA and shall not release more than the prescribed dosage for more than one (1) month to a custodial parent, legal guardian or designated caregiver who, as far as practicable, is a registered nurse licensed by the PDEA to administer dangerous drugs.

An MCC shall comply with this limitation by maintaining internal confidential record of each entry which include information on the date and time the cannabis was dispensed, the amount of cannabis being dispensed and on whether it was dispensed

directly to the patient or to the designated caregiver. Such information shall be protected under R.A. No. 10173, otherwise known as the "Data Privacy Act of 2012".

The hospital's management or its designated agents shall have access to an MCCC's records and premises at any time of the day or night whenever work is being undertaken therein, and to question any employee and investigate any fact, condition or matter which may be necessary to determine violations or which may aid in the enforcement of this Act or its rules and regulations issued pursuant thereto. The PDEA Compliance Service shall also have access to MCCC's records and premises at any time.

**SECTION 12.** Medical Cannabis Research and Safety Compliance Facilities (MCRSCF). – The Medical Cannabis Research and Safety Compliance Facilities (MCRSCF) which include private research laboratories may conduct researches on Medical Cannabis and operate only if they have been issued a valid registration certificate by the DOH.

The DOH shall evaluate applications of Medical Cannabis Research and Safety Compliance Facilities based on the following criteria:

- a) The suitability of the applicant's proposed location including compliance with any local zoning law, agricultural classification and the geographic convenience to patients;
- b) The proposed principal officers' and board members' relevant experiences, including any training or professional licensing related to analytical testing, medicine, pharmaceuticals, natural treatments, botany, or cannabis cultivation, preparation, and testing and their experiences in running a drug testing facility center;
- The sufficiency of the applicant's measures for safety, security, and prevention of diversion, including proposed locations and security devices to be employed; and
- d) The proposed safety compliance facility's procedure for its operations and services, including its staffing and training plans, and sufficiency of capital to operate.

The MCRSCFs should also be compliant with the regulations and requirements of the PDEA Compliance Center.

### SECTION 13. Safety Requirements. - A registered MCRSCF shall:

- a) Implement appropriate security measures to deter and prevent the theft of cannabis and unauthorized entrance into areas containing cannabis;
- Cultivate or test cannabis in an enclosed, locked location at the physical address or addresses provided during the registration process, which can only be accessed by their employees or agents;
- c) Display their registration certificates in their premises at all times; and
- d) Allow PDEA to have continuous access to the facility.

**SECTION 14. Exemption from Civil and Criminal Liability.** – The following shall be exempt from civil and criminal liability:

a) The certifying physician for prescribing medical cannabis or providing written certifications stating that in the physician's professional opinion, a patient is likely to receive therapeutic or palliative benefit from the medical use of cannabis to treat or alleviate the patient's serious or debilitating medical condition or symptoms: Provided, That the physician has established a bona fide relationship with the patient and conducted thorough clinical analysis of the patient's medical conditions;

 A qualified patient for using cannabis in the prescribed dosage for treatment of debilitating medical condition as determined and certified by a bona fide

recommending physician;

 A registered and designated cannabis caregiver for assisting a registered qualified patient and for possessing not more than the exact prescribed dosage of cannabis needed by the qualifying patient;

d) A registered Medical Cannabis Research and Safety Compliance Facility and its agents for possessing and testing cannabis for medical research and

compliance purposes; and

 e) A duly licensed Medical Cannabis Compassionate Centers and its agents authorized to dispense medical cannabis within the hospital premises as provided by Section 11 of this Act.

### SECTION 15. Prohibited Acts. - It shall be prohibited for:

a) A qualified patient to:

1. possess and smoke cannabis and engage in the medical use of cannabis in any

mode of public transportation or in any public place;

 operate, navigate, or being in actual physical control of any motor vehicle, aircraft, or motorboat while under the influence of cannabis: Provided, That a registered qualified patient or visiting qualified patient shall not be considered to be under the influence of cannabis that solely because of the presence of metabolites or components of cannabis that appear in insufficient concentration to cause impairment;

3. undertake, under the influence of cannabis, tasks that would require the use of

body or motor functions impaired by use of cannabis; and

4. use cannabis for purposes other than treatment of a debilitating medical condition.

b) A qualified medical cannabis physician to:

- 1. prescribe medical cannabis to any person who is not a qualified patient under this Act;
- prescribe medical cannabis to any qualified patient without establishing a bona fide relationship with said patient; and

refer patients or caregivers to a MCCC on which he or she holds any financial interest.

c) A registered MCCC to:

- acquire, possess, deliver, transfer, transport, supply, or dispense cannabis to any person except to registered qualified patients or through their registered caregivers;
- acquire usable cannabis or mature cannabis plants from unregistered MCCC;
  and
- 3) refer patients to an unauthorized physician.
- d) Any physician who prescribes medical cannabis to any person or patient without license required in Section 6 of this Act;

- e) Any caregiver, not covered by Section 8 of this Act, who administers medical cannabis to any qualified medical cannabis patient without the required license by the PDEA for the purpose, or who, with license, but administers medical cannabis to a person who is not a qualified medical cannabis patient;
- f) Any person, to include foreigners, to:
  - advertise the sale of medical cannabis in printed materials, on radio or television, social media, or by paid-in-person solicitation of customers. This shall not prevent appropriate signs on the property of the registered MCCC, listings in business directories including phone books, listings in cannabisrelated or medical publications, or the sponsorship of health o rcharity or advocacy events;
  - 2) violate the confidentiality of information under R.A. 10173, otherwise known as the "Data Privacy Act of 2012"; and
  - 3) purchase and access to medical cannabis in oil formulation or in any form not prescribed by the DOH.

**SECTION 16. Penalty.** – Any person who violates any provisions of Section 15 of this Act or its Implementing Rules and Regulations shall, upon conviction and final judgment, be punished with a fine of Fifty Thousand Pesos (P 50,000.00) to One Hundred Thousand Pesos P (100,000.00) or higher at the discretion of the court. Likewise, the same penalty shall be imposed on:

- 1. caregivers in violation of Section 9 of this Act;
- 2. MCCCs in violation of Section 10 and 11 of this Act; and
- 3. MCRSCFs in violation of Sections 12 and 13 of this Act.

In addition, the penalty of imprisonment of six (6) to twelve (12) years shall be imposed on:

- 1. A qualified patient who commits any of the acts proscribed in paragraphs (a) (1) and (a) (4) of Section 15 of this Act;
- 2. A qualified medical cannabis physician who commits any of the act proscribed in paragraph (b) (1) and (a) (4) of Section 15 of this Act;
- 3. A caregiver who commits the proscribed acts in paragraph (e) of Section 15 of this Act; and
- 4. A MCCC which commits the act proscribed in paragraph (c) (1) of Section 15 of this Act: Provided, that the persons liable shall be members of the Board of Directors or Executive Officers of the MCCC, as the case may be.

Furthermore, the penalty shall include suspension or revocation of professional license or registration of the persons or entities held as offenders hereof.

The DOH shall impose administrative sanctions such as suspension or revocation of the license to operate of any private entity found guilty of violating Section 15 of this Act.

The Department shall constitute a Grievance Committee that will review documents and evidence of cases brought to its attention for recommended resolutions for final action of the Secretary.

**SECTION 17. Research.** – The DOH shall, within 120 days from the approval of this Act, authorize the National Institutes of Health, the research arm of the University of the Philippines, Manila; the Health Sciences Center of the UP System, the Philippine Institute of Traditional and Alternative Healthcare (PITACH) and two (2) other organizations it may deem qualified, to conduct research on the use of medical cannabis. Participation to any research program on the part of practitioners, patients, and designated care givers shall be highly encouraged.

Private research laboratories may conduct research studies only if their facilities are duly registered and licensed by the DOH as a MCRSCF.

For purposes of medical research and testing, the Dangerous Drugs Board (DDB) shall formulate the regulations in naming the sources and specifying the methods in accessing the sources of cannabis.

**SECTION 18.** Training of Medical Cannabis Physicians. - The DOH shall provide training programs for medical cannabis physicians which shall include the following topics: overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; and abuse and dependence. The DOH shall coordinate with the Commission on Higher Education to integrate the aforementioned topics on medical cannabis in the medical curriculum of all medical schools, colleges and universities.

**SECTION 19. Reports.** – The Department shall submit to the President of the Philippines and Congress an annual report which shall include the following basic information:

- a) Number of applications and renewals filed for registry identification cards;
- b) Number of registered qualified patients at the time of the report;
- c) Number of registry identification cards that were issued to visiting qualified patients at the time of the report;
- d) Nature of the debilitating medical conditions of the patients;
- e) Number of registry identification cards revoked for misconduct;
- f) Number of authorized physicians who issued written certifications for qualified patients; and
- g) Number of registered MCCCs.

**SECTION 20. Joint Congressional Oversight Committee.** - There is hereby created a Joint Congressional Oversight Committee to conduct a regular review of the implementation of this Act.

The Joint Congressional Oversight Committee shall be composed of five (5) Members from the Senate and five (5) Members from the House of Representatives to be appointed by the Senate President and the Speaker of the House of Representatives, respectively. The Joint Congressional Oversight Committee shall be chaired by the Chairpersons of the Senate Committee on Health and Demography and the House of Representatives Committee on Health.

SECTION 21. Implementing Rules and Regulations. - Within ninety (90) days from the effectivity of this Act, the Secretary of the DOH and the Director-General of PDEA, in

consultation with its Advisory Committee, shall promulgate rules and regulations necessary for the effective implementation of this Act.

**SECTION 22. Separability Clause.** – If any provision or part of this Act is declared invalid or unconstitutional, the remaining parts or provisions not affected shall remain in full force and effect.

**SECTION 23. Repealing Clause.** – For purposes of this Act, pertinent provisions of Republic Act No. 9165, otherwise known as the "Dangerous Drugs Act of 2002", as amended, and all other laws, decrees, orders, rules and regulations, or parts thereof, inconsistent with any provision of this Act are hereby repealed or modified accordingly.

**SECTION 24.** Effectivity. – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,