TWENTIETH CONGRESS OF THE FEDERATED STATES OF MICRONESIA

THIRD REGULAR SESSION, 2018 C.B. NO. 20-142

A BILL FOR AN ACT

To further amend title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, by creating a new chapter 12, to establish the FSM Pharmaceutical Act of 2018, and for other purposes.

BE IT ENACTED BY THE CONGRESS OF THE FEDERATED STATES OF MICRONESIA:

Section 1. Title 41 of the Code of the Federated States of Micronesian (Annotated), as amended, is hereby further amended by creating a new chapter 12 entitled: "Chapter 12. FSM Pharmaceutical Act of 2018"

Section 2. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new subchapter 1 entitled: "General Provisions"

Section 3. Chapter 12 of Title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby further amended by inserting a new section 1201 of subchapter 1, to read as follows:

"Section 1201. Short Title. This Act may be referred to as the FSM Pharmaceutical Act of 2018."

Section 4. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1202 of subchapter 1, to read as follows:

"Section 1202. Definition: For the purposes of this title, the following terms shall be given the meanings described herein:

(1) "Administer" means administering of medicines to a human being either orally or by injection or by introduction into the body in any other way or by external application whether with direct body contact or not.

(2) "Advertising" means the act or practice of calling or bringing public's attention to one's product, services and others especially by paid announcements in print and technology media to promote the sale and use of medicines.

(3) "Alternative medicine" means medical treatments that are used instead of the mainstream conventional medicines, which include finished products and raw materials.

(4) "Competent jurisdictions" mean jurisdictions with stringent and operational regulatory system approved by the Secretary where medicines can be imported. Such approved jurisdictions shall be listed in a record and kept by the Secretary.

(5) "Counterfeit medicines" mean medicines which are intentionally or falsely mislabeled with respect to identity or source.

(6) “Dispensing” means providing medicines by an authorized person licensed to dispense medicines.

(7) “Distribution” means the act of distributing or transferring medicines from a person to another person.

(8) “Establishment” mean a license establishment approved by the Secretary by regulations for, but not limited to, the following:

(a) Wholesales premises;

(b) Distribution channels;

(c) Pharmacies;

(d) Import businesses facilities;

(e) Export business facilities; and

(f) Manufacturing business facilities.

(9) “Exportation” means the process of sending medicines out of FSM by sea or air.

(10) “Finished products” mean products or medicines that have undergone the manufacturing process and are no longer in their basic natural forms.

(11) “FSM Approved Medicines” List means list of medicines that Secretary approved to be imported into and circulated in the FSM.

(12) “Importation” means the lawful process to bringing medicines into the Federated States of Micronesia, by sea or air.

(13) “Inspector” means a person hired, trained, and

certified by the Secretary and regulations to carry out inspection of medicines and establishments.

(14) “Internet pharmacy” means pharmacy that operates over the internet and sends the orders to customers through the mail or shipping companies.

(15) “Manufacturing” means any processing carried out in the course of making the product or medicine.

(16) “Medicinal device” means goods consisting of an instrument, apparatus, appliance, materials or other articles (whether for a use alone or in combination) together to any accessories or software required for its proper functioning, which is intended to be used in, on, or for human beings for therapeutic purpose and which does not achieve its principles intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in such functions by such means.

(17) “Medicines” means substances whether of animal, plant or synthetic origin (not being medicinal device) which are used internally or externally in humans for medicinal purposes including:

(a) Preventing, diagnosing, curing, or alleviating disease, element, defect or injury;

(b) Influencing, modifying or inhibiting of physiological processes;

(c) Testing susceptibility to a disease or ailment;

(d) Influencing, controlling or preventing conception;

(e) Testing for pregnancy or;

(f) Replacement or modification of parts of the anatomy.

(18) "Pharmaceutical sector" is a part of the health sector that deals with, but not limited to:

(a) medicines;

(b) private and government entities and establishments that handles medicines or provide pharmaceutical services;

(c) individuals practicing pharmacy.

(19) "Pharmacovigilance" means the practice of monitoring the effects of medicines, after they have been approved for use, to identify and evaluate previously unreported adverse effects/reactions.

(20) "Person" includes, but is not limited to, an individual, body corporate, companies, organizations, and corporations.

(21) "Raw materials" are basic materials or substances that have not been processed and are still in the form in which they are found in nature which are used alone or in combinations to make medicinal preparations.

(22) “Retailing” means selling of medicines to end users not for resale but for use and consumption by the purchaser.

(23) “Secretary” means the Secretary of Health and Social Affairs, or his or her designee.

(24) “Selling” means providing medicines to another person in exchange for money or something considered to have monetary value.

(25) “Substandard medicines” mean medicines that are of low or poor quality than what it is indicated in the labeling or package inserts.

(26) “Substantial adverse effect” means significant response to a medicine which is harmful and unintended including lack of efficacy and which occurred at recommended human dosage.

(27) “Wholesaling” means selling of medicines in large quantities to resellers at low prices for retailing purposes.

Section 5. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by creating a new subchapter 2, entitled: “Administration”

Section 6. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1203 of subchapter 2,

to read as follows:

"Section 1203. Medicines Unit.

(1) The Secretary shall establish a medicine unit within the Department of Health and Social Affairs to be called the Medicines Unit;

(2) The Medicines Unit's roles and responsibilities shall include coordination of pharmaceutical services and issues with the states, and regulating the pharmaceutical sector by ensuring implementation and enforcement of this Act;

(3) The Medicines Unit shall have one official administrator who shall also be an inspector, and one full time inspector at the inception of the Unit until such time the Secretary recruit more inspectors to enforce this Act by regulations;

(4) Certification of inspectors shall be in compliance with health regulations and policies as established under this Act;

(5) The Medicines Unit shall cooperate in the performance of its function in conjunction with other related established government bodies to carry out its functions."

Section 7. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended to insert a new section 1204 of subchapter 2, to

read as follows:

"Section 1204: National Drug and Therapeutics and Standards Committee.

(1) The Secretary shall establish a Committee to be called the National Drug and Therapeutics and Standards Committee referred to as the Committee.

(2) The purposes of the Committee are to:

(a) advice and assist the Secretary in carrying out her or his duties as provided under this Act, which include;

(i) Establish licensing and inspection requirements;

(ii) Establish policy to provide for the recall of substandard and counterfeit pharmaceutical medicines;

(iii) Establish policy to provide for the monitoring and quality assurance of pharmaceutical medicines;

(iv) Establish regulation or any other legal requirements that may be necessary to support the objectives of this Act;

(b) examine, review, and make recommendations with respect to the issuance, renewal, suspension, or revocation of licenses issued or in effect pursuant to this chapter in accordance with the regulations

established by this Act;

(c) Identify and adopt or develop, where appropriate, treatment guidelines and health standards to be followed;

(d) Perform such other duties and functions as may be lawfully assigned by the Secretary.

(3) The Committee shall consist of ten (10) members which shall include:

(a) One licensed pharmacist from each of the four state health departments and one licensed pharmacist from the national health office;

(b) One licensed physician from each of the four state health departments in the following specialty areas:

(i) Internal medicine

(ii) Pediatrics

(iii) Surgery

(iv) Obstetrics & Gynecology

(c) One representative from the private sector.

(4) All members of the Committee shall be by appointment by the Secretary as recommended by the State Health Directors. All members shall serve the Committee for a six-year term. A vacancy on the Committee shall be filled for the unexpired term by appointment of a successor. The members of the Committee shall elect a

Chairperson, a Vice Chairperson, a secretary and a treasurer, in accordance with the Committee's policy and procedure for such terms as determined by the Committee. Six (6) members of the Committee shall constitute a quorum. Decisions of the Committee shall be made by simple majority votes of the members of the Committee. The chairperson shall schedule regular meetings at locations and times the Chairperson of the Committee may designate in accordance with regulations established under this Act. Special meetings may be called by the Chairperson or Vice Chairperson of the Committee by complying with policy and procedures.

(5) The Committee shall conduct its business affairs in compliance with regulations, policy and procedures established by the Secretary of Health and Social Affairs and the Committee under this Act.

(6) The Secretary may negotiate with other foreign jurisdictions to harmonize regulatory services as may be required from time to time."

Section 8. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended to insert a new section 1205 of subchapter 2, to read as follows:

"Section 1205: Expenses.

(1) Members of the Committee shall be entitled to

necessary travel expense and to per-diem at standard FSM rates while on the business of the Committee. Any member of the Committee currently employed by the national or state government shall be granted administrative leave to attend the business of the Committee and shall receive his or her regular salary while under the business of the Committee."

Section 9. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new subchapter 3, entitled: "Medicines"

Section 10. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1206 of subchapter 3, to read as follows:

"Section 1206: Market Authorization.

(1) Medicines sold in the supply chain shall be regulated by the Secretary.

(2) The Secretary shall establish a FSM Approved Medicines List which will be reviewed every two years. The Approved Medicines List can also be reviewed annually depending on the need or upon request. Only medicines listed on the approved medicines list shall be imported into the Federated States of Micronesia.

(3) The Secretary shall establish a registration

system for imported medicines. Medicines already registered in competent jurisdictions with stringent regulatory measures or medicines from other jurisdictions that meet the standards of the WHO prequalification scheme and are included on the FSM Approved Medicines List may be exempted from the registration.

(4) The Secretary shall establish a strategic plan and mechanism for laboratory quality assurance testing for medicines moving through the supply system by using quality methods recognized by regulations.

(5) The Secretary shall establish a National Medicine Schedule that will control or regulate how medicines are made available to the public. Approved medicines shall be scheduled in a category of medicines in accordance with the National Medicine Schedule."

Section 11. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1207 of subchapter 3, to read as follows:

"Section 1207: Handling of Medicines.

(1) Only medicines approved by the Secretary shall be imported, distributed, exported, stored, supplied, prescribed, dispense, and sold.

(2) All imported medicines shall have all required

documentation and certificates of analysis and shall be inspected upon their arrival and at their establishments when required in accordance with inspection or verification procedural processes established by regulation under this Act.

(3) Only registered license holders shall be eligible to procure, import, distribute, export, store, supply, prescribe, dispense, and sell medicines in accordance with the scope of their licenses.

(4) The transportation and maintenance of distributed medicines shall be in accordance with established regulation as may be varied from time to time by the Secretary.

(5) Procurement, storage, prescribing, dispensing, counseling, book keeping and disposal practices shall be in accordance with the best practices in the industry and by regulation.

(6) Licensed establishments and health institutions shall keep all records of medicines for a certain period of time as may be established by regulations."

Section 12. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1208 of subchapter 3, to read as follows:

"Section 1208: Labeling, Packaging, Advertisement or

Promotion.

(1) All medicines must be clearly labeled and packaged to ensure that medicines are correctly described, readily identifiable and safe use is promoted.

(2) All imported and dispensed medicines and authorized handlers of medicines shall comply with labeling, packaging, advertising, and promotional requirements established by regulation and health policies, which shall set standards and requirements on the subject matters and other related items."

Section 13. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1209 of subchapter 3, to read as follows:

"Section 1209: Medicine Information.

(1) Licensed dispensers or sellers of medicines are required to provide patient counseling at all times when a medicine is dispensed to the patient or sold to a customer.

(2) Information on different types of medicine and the disseminating of information of the medicines to health institutions, relevant health workers, and patients shall be in compliance with relevant legislation, health regulations, and policies.

(3) Applicable research findings shall be integrated into the monitoring and evaluation system to enhance medical practices, policies, and regulations."

Section 14. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1210 of subchapter 3, to read as follows:

"Section 1210: Pharmacovigilance.

(1) The Secretary shall establish a medicines adverse effect monitoring and reporting system to safe guard public health, and collect adverse effect data for research and decision-making purposes.

(2) If at any time any dispenser of medicines or a person permitted to administer medicines has reason to believe that a substantial adverse reaction has risen from the use of the medicine, the said individual shall immediately notify the Secretary the nature of such effects and the circumstances in which they arose."

Section 15. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended is hereby further amended by inserting a new section 1211 of subchapter 3, to read as follows:

"Section 1211: Medicine Recall.

(1) The Secretary shall establish a system for medicine recall to ensure:

(a) The recall of substandard or counterfeit medicines;

(b) And that information on such recalls are disseminated to the public in a timely manner."

Section 16. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by creating a new subchapter 4, entitled: "Establishments"

Section 17. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1212 of subchapter 4, to read as follows:

"Section 1212: Licensing.

(1) All establishments are prohibited from handling medicines unless duly licensed by the Secretary.

(2) The Secretary shall establish regulations which shall set forth requirements and criteria for licensing, and code of conduct or a professional standard for establishments or persons involved in the handling of medicines in relation to importation, distribution, exportation, manufacturing, wholesaling, retailing, advertising and promotion.

(3) The Secretary shall also have the power to renew, suspend, or revoke licenses.

(4) The Secretary or his or her designee shall have

the power to perform unannounced inspections at establishments that handle medicines and also perform random sampling of medicines for quality assurance.

(5) A license holder shall report to the Secretary of any change of address of business, change of ownership of business and the date where business will cease to operate."

Section 18. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1213 of subchapter 4, to read as follows:

"Section 1213: License Fees.

(1) The Secretary with advice of the Committee may by regulation require that a fee be paid by applicants for licenses or renewal of licenses. Fees shall be dealt with by the Secretary in accordance with established regulations and policies."

Section 19. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is further hereby amended to insert a new section 1214 of subchapter 4, to read as follows:

"Section 1214. Display and Record of Licenses.

(1) Licenses shall be posted in a prominent location at the license establishments or premises. A permanent record of each license and each renewal thereof shall be

kept in a record by the Secretary."

Section 20. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1215 of subchapter 4, to read as follows:

"Section 1215: Revocation or Suspension of Licenses. Any license issued or in effect pursuant to the provisions of this chapter or provisions of regulations established under this chapter may be revoked or suspended for cause by the Secretary. The Secretary may take other such disciplinary actions against the license holder in accordance with the provisions of chapter 1, of the Title 17 of the FSMC as she or he finds appropriate. FSMC shall apply to such action. Upon a revocation or suspension or their becoming final all pharmaceutical medicines shall be forfeited to the FSM government and shall be dealt with by the Secretary in accordance with established regulations and policies."

Section 21. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1216 of subchapter 4, to read as follows:

"Section 1216: Confidentiality of Records.

(1) All information provided to the Secretary by any

source in connection to official activities of the Unit or the Committee shall be kept confidential and shall be released only in response to subpoena or court order or administrative order provided, however, that such sources shall have access to their records in accordance with policy and procedures established by regulations and legislation.

(2) Whistle blowers shall be protected by regulations and policy and procedure.

Section 22. Chapter 12 of title 41 of the Code of the Federated States of Micronesia, (Annotated), as amended, is hereby further amended by inserting a new subchapter 5, entitled: "Manufacturing"

Section 23. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1217 of subchapter 5, to read as follows:

"Section 1217. Unless permitted by the Secretary, applicable legislation, health policy and regulation, the manufacturing of medicines is prohibited".

Section 24. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new subchapter 6, entitled: "Internet Pharmacy"

Section 25. Chapter 12 of title 41 of the Code of the

Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1218 of subchapter 6, to read as follows:

"Section 1218. Unless permitted by the Secretary, applicable or relevant legislations, national health policies and regulations, Internet Pharmacy is strictly prohibited."

Section 26. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new subchapter 7, entitled: "Alternative Medicines"

Section 27. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1219 of subchapter 7, to read as follows:

"Section 1219: Finished Products.

(1) For the purpose of this Act, finished products proclaiming to have healing effects will be treated and regulated as medicines unless otherwise directed by the Secretary, relevant legislations, regulations and health policies."

Section 28. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1220 of subchapter 7, to read as follows:

"Section 1220: Raw materials.

(1) Any raw materials for medicine imported from foreign jurisdictions shall have the name of the raw material and clearly labeled and packed in appropriate containers depending on the nature of the raw materials."

Section 29. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new subchapter 8 entitled: "General Offenses and Penalties"

Section 30. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby further amended by inserting a new section 1221 of subchapter 8, to read as follows:

"Section 1221. Penalties for any wilful or unintended conduct in violation of the provisions of this Act shall be regulated by the Secretary."

Section 31. This act shall become law upon approval by the President of the Federated States of Micronesia or upon its becoming law without such approval.

Date: 2/6/18 Introduced by: /s/ Florencio S. Harper
Florencio S. Harper
(by request)