TWENTY-SECOND CONGRESS OF THE FEDERATED STATES OF MICRONESIA

SECOND SPECIAL SESSION, 2021 C.B. NO. 22-100

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 2021, 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 Micronesia (Annotated), as amended, is hereby further amended by creating a new chapter 12 entitled: "FSM Pharmaceutical Act of 2021".

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), as amended, 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 2021.".

Section 4. Chapter 12 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. Statement of Policy.

It is hereby declared a as a policy of the Federated States of Micronesia:

(1) That all people have the right to access quality, safe, effective and affordable medicines;

(2) That a national regulatory authority shall be established and progressively strengthened to administer and enforce regulations of all pharmaceutical products to ensure acceptable standards of quality, safety and efficacy; regulate promotion and marketing to ensure rational drug use; and ensure compliance with standards and requirements for all personnel, business establishments , premises and practices in the storage, supply and distribution, sale, prescription and dispensing of pharmaceutical products;

(3) That the national regulatory authority shall, to the extent possible, participate in regulatory convergence and cooperation as a means to strengthen the FSM regulatory system and cooperate with regulatory authorities in other countries as appropriate, to align regulatory processes where needed to tackle public health emergencies, and address the proliferation of substandard, falsified and unlicensed products across borders."

Section 5. 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 1 to read as follows:

"Section 1203. Definitions.

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) "Authorized port-of-entry" means a port of entry designated by the government where medicines may enter or leave under official supervision of relevant government authorities. An authorized port-of-entry for medicines shall be selected from ports of entries designated under 18 F.S.M.C. § 202.

(4) "Certificate of pharmaceutical product (CPP)" is a certificate issued in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product and of the applicant for this certificate in the exporting country. The certificate attests that a specific pharmaceutical

product is authorized for marketing in the certifying country, or if not, the reason why authorization has not been accorded; and the manufacturing facilities and operations conform to good manufacturing practices (GMP) as recommended by WHO. A CPP is issued by the authorized body of the exporting country and is intended for use by the national regulatory authority or other competent bodies in the Federated States of Micronesia when a pharmaceutical product is under consideration for a product license/registration that will authorize its importation and sale in FSM and when administrative action is required to renew, extend vary or review such license.

(5) "Clinical Trial" is any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

(6) "Competent authority" means a regulatory body authorized by the government to administer, implement and enforce regulations and compliance to national laws and carry out duties on behalf of the government.

(7) “Complementary medicine (CAM)” often refers to a broad set of health care practices that are not part of a country’s own tradition and are not integrated into the dominant health care system. Other terms sometimes used to describe these health care practices include “natural medicine”, “nonconventional medicine” and “holistic medicine”.

(8) “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.

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

(10) “Distribution” means the division and movement of pharmaceutical products from the premises of the manufacturer/supplier of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

(11) “Donation” pertains to the act by which organizations, institutions, international development partners, non-government organizations and other legal entities within and outside FSM provide pharmaceutical

products to the government for free and for specific use, such as in the case of emergencies or humanitarian purposes.

(12) "Establishment" means a licensed establishment or entity approved under this Act to engage in the trade, distribution of pharmaceuticals and other products regulated under this Act. It includes, but not limited to the following:

(a) Wholesalers;

(b) Pharmacies;

(c) Importers;

(d) Exporters;

(e) Warehouse operators;

(f) Packaging;

(g) Retailers.

(13) "Exportation" means the process of sending medicines out of FSM by sea or air.

(14) "Finished product" is a product that has undergone all stages of production, including packaging in its final container and labeling and are no longer in their basic natural forms.

(15) "FSM Approved Medicines List" means list of medicines determined to meet the needs of the population of FSM and approved by the Secretary to obtain registration in FSM and to be imported into and

circulated in the FSM.

(16) "Importation" means the lawful process of bringing medicines into the Federated States of Micronesia by sea or air.

(17) "Importer" is an individual or company or similar legal entity importing or seeking to import a pharmaceutical product. A "licensed" or "registered" importer is one who has been granted a license or registration status for the purpose. The license or registration of an importer does not automatically grant the importation of any medicinal/pharmaceutical product/s in the country as products to be imported shall be subject to a separate process of registration as regulated by this Act.

(18) "Inspection" is an official examination, usually conducted on-site by a relevant authority to determine compliance to regulations, standards and good practices for, but not limited to, pharmaceutical establishments; warehouses; ports or any other entity engaged in the trade and supply of pharmaceutical products as well as establishments providing pharmaceutical services.

(19) "Internet pharmacy" means pharmacy that operates over the internet or is involved in trading of pharmaceutical products online.

(20) "Manufacturing" includes all operations of

receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage and distribution of active pharmaceutical ingredients and related controls.

(21) “Product License/Registration” is a legal document issued under this Act, for the purpose of marketing or free distribution of a medicinal product after evaluation for safety, efficacy and quality and the needs of the people in FSM. Once a product has been registered/licensed, it is included on a list of authorized products — the register — and is often said to be "registered" or to "have registration".

(22) “Medicines regulatory authority (or National Regulatory Authority)” is a body created under this Act to administer and enforce the full spectrum of pharmaceutical regulations, including but not limited to the following: registration of new products and variation of existing products; quality control laboratory testing; pharmacovigilance; provision of medicine information and promotion of rational medicines use; inspections and licensing of wholesalers, pharmacies, importers and exporters; enforcement operations and monitoring of medicines utilization and all other regulations that are deemed necessary in ensuring the safety, quality, and efficacy of

pharmaceuticals.

(23) "Over-the-counter medicines (non-prescription medicines)" are medicines that can be sold from licensed dealers without professional supervision and without prescription. These medicines are suitable for self-medication for minor disease and symptoms.

(24) "Pharmaceutical (medicine, drug)" is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms drug, medicine, pharmaceutical, and pharmaceutical product(s) are used interchangeably, and shall include, medicines, vaccines, biologicals and/or other products with proven therapeutic effect. Any product entered and sold into FSM with a therapeutic claim shall be treated and regulated as a pharmaceutical product and shall conform to all the requirements and regulations under this Act.

(25) "Pharmacopeia" or "International Pharmacopoeia" constitutes a collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances and dosage forms that is intended to serve as source material to establish pharmaceutical requirements.

(26) “Pharmacovigilance” is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.

(27) “Person” includes, but is not limited to, an individual, body corporate, companies, organizations, and corporations.

(28) “Prequalification” means the activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the decision. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the procurement agency may

differ.

(29) “Prescription” means an order mostly in written form by a licensed/qualified health care professional to a pharmacist or other therapist for a medicine or treatment to be provided to their patients.

(30) “Procurement” is the process of acquiring supplies, including those obtained by purchase, and donation.

(31) “Promotion” refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

(32) “Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of pharmaceuticals.

(33) “Recalls” are actions taken to remove a pharmaceutical product from the market which do not conform to established standards of quality, safety and efficacy, and/or harmful to the public and/or unlicensed by the national regulatory authority of FSM.

(34) “Recognition” means the acceptance of the regulatory decision of another regulatory authority of another country.

(35) “Regulatory cooperation” means the mechanism whereby the pharmaceutical regulatory authority

established under this Act shall work with other relevant regulatory authorities, agencies or institutions within the country or in other countries in order to efficiently and effectively regulate pharmaceutical products. Regulatory cooperation may also include working with international counterparts to build regulatory capacity or provide technical assistance in the implementation and/or enforcement of its functions.

(36) "Reliance" is the act whereby the regulatory authority established in the Act shall take into account the evaluations performed by other regulatory authorities as a basis for decision making.

(37) "Regulatory convergence" means a voluntary process whereby the regulatory requirements in different countries or regions become more similar or "aligned" over time. The process results from the gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures, or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.

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

(39) "Sampling" means an operation designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose.

(40) "Secretary" means the Secretary of Health and Social Affairs, or his or her designee.

(41) "Wholesale" means all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public.

(42) "WHO certification scheme". The WHO Certification Scheme offers to importing countries information about: a) the status of the pharmaceutical product; b) the status of the manufacturer of the pharmaceutical product; c) the quality of individual batches of the exported pharmaceutical product; d) product information as approved in the country of export."

Section 6. 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: "Scope of

the Law".

Section 7. 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 1204 of subchapter 2 to read as follows:

"Section 1204. Pharmaceutical Products.

All pharmaceutical products, including, but not limited to medicines, vaccines, biopharmaceuticals, blood and blood products, and any other products with therapeutic claims shall be a regulated under this law. Traditional or local medicines and practices are not regulated under this law."

Section 8. 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 1205 of subchapter 2 to read as follows:

"Section 1205. Pharmaceutical Activities.

All pharmaceutical activities including but not limited to the manufacture, importation, exportation, wholesaling, supply and retailing, labeling and packaging, advertisement and marketing, clinical trials, and donations shall be regulated under this law."

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 section 1206 of subchapter 2 to

read as follows:

"Section 1206. Practice of pharmacy.

The practice of pharmacy, including but not limited to dispensing and prescribing shall be regulated under this law. The use of pharmaceutical products shall strictly follow regulations under this Act, other relevant laws and other subsequent guidance that will be issued by competent authorities in FSM."

Section 10. 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 3 entitled: "Administration".

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. Pharmaceutical Unit.

(1) The Secretary shall establish a structure/unit within the Department of Health and Social Affairs to be called the Pharmaceutical Access, Standards and Regulatory Unit, to be headed by a coordinator, otherwise known as the Pharmaceutical Unit. The unit shall have the following functions:

(a) Administrative Functions:

(b) Regulatory Functions:

(c) Inspectoral/Inspectorate Functions:

(d) Quality Assurance Functions:

(2) The Unit shall have the power to recall substandard, falsified, and unlicensed/unregulated medicines. It shall also have the power to ensure that importers are accountable for the quality and safety of their imported medicines and that doctors/healthcare providers monitor and report adverse drug events and/or reactions for appropriate actions to safeguard public health."

Section 12. 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: "Regulatory Cooperation".

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 1208 of subchapter 4 to read as follows:

"Section 1208. Regulatory Cooperation.

(1) The Secretary shall establish a system for recognition, reliance, convergence and cooperation with other regulatory bodies within and outside the country, which may aid the FSM Pharmaceutical Unit in the performance of its functions and in the implementation and enforcement of this Act;

(2) The Secretary, upon recommendation of the Pharmaceutical Unit, shall determine the list of regulatory authorities and regional and global convergence mechanisms abroad, upon which recognition, reliance, convergence and cooperation can be undertaken."

Section 14. 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 5 entitled: "Regulation of Pharmaceutical Products".

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 1209 of subchapter 5 to read as follows:

"Section 1209. FSM Approved Medicines List.

(1) The Secretary shall establish the FSM Approved Medicines List. Only medicines listed on the approved medicines list shall be imported and registered in the Federated States of Micronesia.

(2) Other pharmaceutical products which are not in the approved medicines list may be registered upon certification of need by the States' Drug Therapeutic Committees or other relevant national committees and upon approval by the Secretary for inclusion in the approved medicines list.

(3) Pharmaceutical products for public health emergencies and for compassionate use, not otherwise contained in the FSM Approved List, may be granted exemption from this provision upon recommendation of relevant committees/organizations and upon certification by the Secretary.

(4) The FSM Approved Medicines List shall be reviewed every two years or as often as necessary as the need arises."

Section 16. 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 5 to read as follows:

"Section 1210. Medicine License/Registration.

(1) All pharmaceutical products used for the prevention, diagnosis, treatment, management and care for medical conditions, shall be registered before they are imported, sold, and distributed in the Federated States of Micronesia.

(2) The Secretary shall establish a registration system for pharmaceutical products and a protocol for the appraisal, review and evaluation of products for registration. Pharmaceutical products 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 review process.

(3) The criteria and conditions for registration shall be regulated by established policies and regulations.

(4) Specific criteria and procedure for registration for new chemical entities and variations to existing medicine license/registration shall be regulated by established policies and regulations.

(5) The Secretary may call upon independent experts and/or technical partners to assist the pharmaceutical unit in the evaluation of applications for medicine registration.

(6) The Secretary shall determine the level of fees for the evaluation of application for medicine registration.

(7) Upon the establishment of the registration process, the Secretary shall require the conduct of market inventory to determine the products that are already available and/or circulating in the market.

(8) Medicine license/registration may be suspended or revoked for cause by the Secretary."

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 1211 of subchapter 5 to read as follows:

"Section 1211. Entry of pharmaceutical products for public health emergency and live saving medicinal products.

(1) The Secretary shall establish a facilitated and streamlined mechanism for the entry of pharmaceutical products for public health emergencies and life-saving medicines which are not registered in the Federated States of Micronesia;

(2) The use of pharmaceutical products under this Section shall be placed under strict control and monitoring by the Pharmaceutical Unit.

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 1212 of subchapter 5 to read as follows:

"Section 1212. Pharmaceutical Products for Personal Use.

Pharmaceutical products intended for personal use may be allowed entry into the country, upon full satisfaction of the following:

(1) Product is not for treatment of a serious condition and there is no known significant health risk (Over the Counter, OTC); and

(2) If product is a prescription drug; it must satisfy the following:

(a) The product must be accompanied by a prescription from a licensed physician in FSM or if the product is a continuation of a treatment obtained from a foreign country, a certification from the physician in that country who has administered the treatment;

(b) The product will not be commercialized or distributed to other persons in FSM;

(c) The consumer affirms in writing that the product is for personal use; and

(d) The quantity is generally not more than a three month supply."

Section 19. 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 5 to read as follows:

"Section 1213. Donations.

Only products contained in the FSM Approved List will be accepted for donations in FSM. All donations will be subject to regulations under this act. Donations that are not in the FSM Approved List shall be treated under Section 1209 of this Title."

Section 20. 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 6 entitled: "Quality Assurance".

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 1214 of subchapter 6 to read as follows:

"Section 1214. Quality Assurance.

(1) Pharmaceutical standards: The International Pharmacopoeia and other pharmacopoeias recognized by the Pharmaceutical Unit of FSM may be used as the basis for compendial standards for quality testing of pharmaceutical products in FSM.

(2) The Secretary shall establish a strategic plan and mechanism for quality assurance of medical products in the market including laboratory testing and analysis of drug samples, in a competent pharmaceutical control laboratory."

Section 22. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 7 entitled: "Importation of Medicines."

Section 23. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1216 of subchapter 7 to read as follows:

"Section 1215. Importation of Medicines.

(1) Only medicines included in the FSM Approved List

and are registered shall be imported, distributed, exported, stored, supplied, prescribed, dispensed, and sold in FSM.

(2) All imported medicines shall have all required documentation, including among others, certificate of pharmaceutical product or product registration, certificates of analysis and other documents that may be required by the Unit or the Secretary.

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

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

Section 24. 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 8 entitled: "Port of Entry for Pharmaceutical Products."

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 1216 of subchapter 8 to read as follows:

"Section 1216. Designation of a Port of Entry for Pharmaceutical Products.

(1) The Secretary, in coordination with the Department of Finance and Administration and/or other relevant departments or agencies, shall designate the port of entry of pharmaceutical products into the Federated States of Micronesia. The authorized port of entry for pharmaceutical products shall be selected from designated ports of entries under 18 F.S.M.C. § 202. No new ports of entry shall be designated under this section other than the ports of entries already designated under existing law.

(2) The Secretary shall cause the inspection of all pharmaceutical products at the port-of-entry or at the establishments, to verify the validity of their registration in FSM.

(3) Pharmaceutical products that entered into the Federated States of Micronesia outside the designated port of entry shall be subjected to seizure, quarantine and destruction by the competent authorities."

Section 26. 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 9 entitled:

"Establishments."

Section 27. 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 9 to read as follows:

"Section 1217. Licensing of Establishments Required.

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

(2) 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, exportation, wholesaling, retailing, advertising and promotion shall be regulated by established regulations.

(3) 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.

(4) 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 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 1218 of subchapter 9 to

read as follows:

"Section 1218. License Fees.

The Secretary, with advice of relevant committees/organizations, may by regulation require that a fee be paid by applicants for licenses or renewal of licenses. Fees shall be payable upon application or such other times as is determined by the Secretary. Such fees may be different for the different categories of licenses as prescribed by the Secretary and such fees may change from time to time."

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 section 1219 of subchapter 9 to read as follows:

"Section 1219. Display and Record of Licenses.

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 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 1220 of subchapter 9 to read as follows:

"Section 1220. Revocation or Suspension of Licenses.

(1) 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.

(2) 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 31. 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 9 to read as follows:

"Section 1221. Confidentiality of Records.

(1) All information provided to the Secretary by any source in connection to official activities of the Unit or relevant committees 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 32. 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 10 entitled: "Manufacturing."

Section 33. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1222 of subchapter 10 to read as follows:

"Section 1122. Manufacturing.

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

Section 34. 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 11 entitled: "Internet Pharmacy."

Section 35. 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 1223 of subchapter 11 to read as follows:

"Section 1223. Internet Pharmacy.

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

Section 36. 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 12 entitled: "Complementary Medicines."

Section 37. 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 1224 of subchapter 12 to read as follows:

"Section 1224. Finished Products.

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 38. 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 13 entitled: "General Offenses and Penalties."

Section 39. 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 1225 of subchapter 13 to read as follows:

"Section 1225. Penalties.

(1) Any willful violation of any provision of this chapter is subject to a fine of $3,000 up to $15,000

and/or imprisonment of up to five (5) years.

(2) Where an offense is committed by a corporation or legal entity, the maximum fine is up to $100,000; and where a violation by a corporation or legal entity resulted in a serious injury or death of a person, the maximum fine is up to $200,000."

(3) The Secretary may issue regulation to implement this section and any other provision of this chapter."

Section 40. 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: 11/12/21 Introduced by: /s/ Florencio S. Harper
Florencio S. Harper
(by request)