TWENTIETH CONGRESS OF THE FEDERATED STATES OF MICRONESIA

FOURTH REGULAR SESSION, 2018 C.B. NO. 20-195

A BILL FOR AN ACT

To further amend Title 41 of the Code of the Federated States of Micronesia (Annotated), 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), is hereby amended by creating a new chapter 12 entitled: "FSM Pharmaceutical Act of 2018".

Section 2. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby 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 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), is hereby amended by inserting a new section 1202 of subchapter 1 to read as follows:

"Section 1202. Statement of Policy. It is hereby declared 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; control use of antimicrobials; and ensure compliance to standards and requirements for all personnel, business establishments , premises and practices in the manufacture, 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, including antimicrobial resistance 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), is hereby amended by inserting a new section 1203 of subchapter 1 to read as follows:

"Section 1203. Definition: For the purposes of this

title, the following terms shall be given the meanings described herein:

1. “Active Pharmaceutical Ingredient” (API) is the chemical substance contained in a pharmaceutical, which is responsible for its therapeutic effect. Some pharmaceuticals contain more than one active ingredient (combination product).

2. “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.

3. “Adverse drug reaction” (ADR) is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. An adverse drug reaction, contrary to an adverse event, is characterized by the suspicion of a causal relationship between the medicine and the occurrence. *Serious adverse reaction*: An adverse reaction which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or

is a congenital anomaly/birth defect. *Unexpected adverse reaction*: An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

4. "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.

5. "Authorized port-of-entry": An authorized port-of-entry is a port designated by the government where medicines may enter or leave under official supervision of relevant government authorities.

6. "Authorization holder" means the person or company in whose name the marketing authorization has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorization. The authorization holder must be physically present in the country and be subject to all the rules and regulations of the country.

7. "Brand name" or "innovator`s name" Name given for marketing purposes to any ready-prepared medicine placed on the market under a special name and in a special pack. A brand name may be a protected

trademark

8. "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/marketing authorization that will authorize its importation and sale in FSM and when administrative action is required to renew, extend vary or review such license.

9. " 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.

10. "Competent authority" 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.

11. "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.

12. "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.

13. "Controlled Medicine" or "Controlled Substance" means medicine/drug, substance or immediate precursor in schedules I through V of subchapter II of chapter 11 of Title 11 of the Code of the Federated States of Micronesia

14. "Dispensing" means providing medicines by an authorized person licensed to dispense medicines.

15. "Disposal" in this act means the action or process of getting rid of expired, damaged, deteriorated, or unwanted medicines/pharmaceutical products.

16. "Distribution" means the division and movement of pharmaceutical products from the premises of the manufacturer 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.

17. "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.

18. "Dosage form". The form of the completed pharmaceutical product, e.g. tablet, capsule, elixir, injection or suppository.

19. "Drug and therapeutics committee" is a group of people established and officially approved by the Secretary of Health and Social Affairs or State health

Directors that promotes the safe and effective use of medicines in the area or facility under its jurisdiction.

20. "Essential medicines" are medicines that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

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

a. Wholesalers;

b. Distributors;

c. Pharmacies;

d. Importers

e. Exporters

f. Manufacturers

g. Warehouse operators

h. Packaging

i. Retailers

1. "Exportation" means the process of sending medicines out of FSM by, sea or air.

24. "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.

25. "Formulary". A formulary is a manual containing clinically oriented summaries of pharmacological information about selected drugs. A national formulary generally includes available and affordable medicines that are relevant to the treatment of diseases. It may also include administrative and regulatory information pertaining to the prescribing and dispensing of drugs.

26. "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 marketing authorization in FSM and to be imported into and circulated in the FSM,

27. "Generic" is a pharmaceutical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ

significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Generics can be classified in branded generics (generics with a specific trade name) and unbranded generics (which use the international non-proprietary name and the name of the company).

27. "Importation" means the lawful process of bringing medicines into the Federated States of Micronesia, by sea or air.

28. "Importer". An 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/marketing authorization as

regulated by this Act.

29. "Good manufacturing practices" (GMP) is the element of quality management which ensures that products are consistently produced and controlled according to the quality standards appropriate of their intended use and as required by the marketing authorization, clinical trial authorization or product specification. It is aimed at managing and minimizing the risks inherent in pharmaceutical manufacture in order to ensure the quality, safety and efficacy of products.

30. "Good distribution practice" (GDP) is part of quality assurance which ensures that the quality of pharmaceuticals is maintained throughout the numerous activities occurring during the distribution process. It encompasses the following elements: maintain a constant supply of drugs, keep pharmaceuticals in good condition through the distribution process, minimize pharmaceutical losses due to spoilage and expiry, maintain accurate inventory records, rationalize drug storage points, use available transportation resources as efficiently as possible, reduce theft and fraud, and provide information for forecasting pharmaceuticals needs.

31. "Good pharmacy practice" is the practice of

pharmacy aimed at providing and promoting the best use of drugs and other health care services and products by patients and members of the public.

32. "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.

33. "Inspector" means a person designated, upon appropriate training and certification, to carry out inspection of medicines and establishments. Certification of inspectors shall be in compliance with health regulations and policies as established under this Act.

34. "International non-proprietary name" (INN) or "generic name" is a unique name that is globally recognized as the unique and universally available designated name to identify each pharmaceutical substance. INN is used in the international nomenclature for the clear identification, safe prescription and dispensing of medicines to patients, INNs are intended for use in pharmacopoeias, labeling,

product information, advertising and other promotional material, medicine regulation and scientific literature, and as a basis for product names.

34. “Internet pharmacy” means pharmacy that operates over the internet or is involved in trading of pharmaceutical products online.

35. “License holder for pharmaceutical product” is an individual or entity duly registered under this Act who holds a marketing authorization for a pharmaceutical product.

36. “Licensing system” is a national legal requirement provided for in this Act on who should manufacture, import or supply pharmaceuticals products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products.

37. “Manufacturer” is a natural or legal person with responsibility for manufacturing of a product.

39. “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.

40. “Marketing authorization (registration)” is a legal document issued under this Act, for the purpose

of marketing or free distribution of a product after evaluation for safety, efficacy and quality and the needs of the people in FSM. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be "registered" or to "have registration". Market authorization may occasionally also be referred to as a "license" or "product license".

41. "Medication error" is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

42. "Medicine Information". For the purpose of this Act, medicine information will include but not limited to:

a. Medicine description (generic name; strength; dosage form/formulation; etc)

b. Indication

c. Adverse Effects

d. Warnings

43. “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: marketing authorization of new products and variation of existing products; quality control laboratory testing; pharmacovigilance; provision of medicine information and promotion of rational medicines use; enforcement of Good Manufacturing Practice (GMP); inspections and licensing of manufacturers, wholesalers, pharmacies, importers, exporters and distributors; enforcement operations and monitoring of medicines utilization and all other regulations that are deemed necessary in ensuring the safety, quality, and efficacy of pharmaceuticals.

44. “Medicinal device” means goods consisting of an instrument, apparatus, appliance, materials or other articles (whether for a use alone or in combination) together with 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.

45. "National Essential Medicines List" is the list of essential medicines that has been defined and adopted by the National Drug Therapeutics Committee through an evidence-based process and approved by The Secretary which includes all pharmaceutical and therapeutic products that meets the need of the people of FSM. The list shall be the basis for marketing authorization, importation, and procurement by health service providers and reimbursement by health insurance.

46. "National medicines policy (NMP)". The national medicine policy of FSM embodies the commitment, goal and strategic direction for improving access to quality, safe and effective essential medicines for the people of FSM. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. The NMP may be reviewed from time to time as the need arises.

47. "New chemical entity (NCE)" is a chemical

molecule developed by the innovator company in the early discovery stage, which after undergoing clinical trials could translate into a pharmaceutical that could be a cure for some disease.

48. "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.

49. "Pharmaceutical (medicine, drug)". A pharmaceutical 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, and pharmaceutical are used interchangeably, and shall include, medicines, vaccines, traditional medicines, 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.

50. "Pharmaceutical form" is the pharmaceutical-technological form in which an active substance is

made available. Pharmaceutical may be administered in solid form (e.g. tablets, powers), in semi-liquid form (e.g. ointments, pastes), in liquid form (e.g., drops, injectables, infusions) or in gaseous form (inhalation).

52. "Pharmaceutical product" is a unique product defined by its active pharmaceutical ingredient, the strength of the active pharmaceutical ingredient, its pharmaceutical form and route of administration.

53. "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.

54. "Pharmacists" are persons who have completed studies in pharmacy at university level (granted by adequate diploma) and who are licensed to practice pharmacy.

55. "Pharmaceutical sector" is a part of the health sector that deals with, but not limited to:

a. Medicines; vaccines and biological products; diagnostics; traditional medicines and other medicinal/pharmaceutical products

b. Private and government entities and

establishments that handles medicines or provide pharmaceutical services;

c. Individuals practicing pharmacy.

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

57. “Pharmacy” or “Pharmacies” are premises which in accordance to the local legal provisions and definitions may operate as a facility in the provision of pharmacy services in the community or health facility setting.

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

59. “Post-marketing surveillance” is the testing of medicine samples to assess the quality of medicines that have already been licensed for public use.

60. “Prequalification”. 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.

61. "Prescriber". A prescriber is a health care professional who is legally qualified to write a prescription.

62. "Prescription" is an order mostly in written form by a qualified health care professional to a pharmacist or other therapist for a medicine or treatment to be provided to their patients.

63. "Prescription-only medicines" are medicines supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for

animal treatment only) and/or other health professionals allowed to prescribe in FSM and the supply and dispensing of these medicines must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription-only medicines are further subdivided into controlled medicines (narcotic medicines and psychotropic substances) and non-controlled medicines.

64. "Procurement" is the process of acquiring supplies, including those obtained by purchase, donation, and manufacture.

65. "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.

66. "Quality assurance" is a wide-ranging concept covering all matters that individually or collectively influence the quality of pharmaceuticals.

67. "Quality control" are all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength,

purity and other characteristics.

68. "Rational use of medicines". Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

69. "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.

70. "Recognition" is the acceptance of the regulatory decision of another regulatory authority of another country.

71. "Regulatory cooperation is 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.

72. "Regulatory Inspection" is an officially conducted examination (i.e. review of quality assurance processes, personnel involved, any delegation of authority and audit) by relevant authorities at sites where pharmaceutical activities take place (i.e. manufacturing, wholesale, testing, distribution, clinical trials) to verify adherence to Good Practices.

73. "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.

74. "Regulations" are the set of instruments provided under this Act and other relevant laws and regulations of the Federated States of Micronesia by which the government places and enforces requirements and standards for establishments, products and individuals to ensure the quality, safety, efficacy and appropriate use of pharmaceuticals.

75. "Regulatory convergence" is 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.

76. “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.

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

78. “Standard operating procedure (SOP)” is an authorized written procedure providing a documented process to follow in a specific situation.

79. “Sample”. A sample is a portion of a material or a pharmaceutical product collected according to a defined sampling procedure.

80. “Sampling”. Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose.

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

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

83. “Specification” is a list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

84. “Standard treatment guidelines” (STGs) are recommended and standardized treatment protocols for commonly occurring conditions.

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

86. “Summary of product characteristics” (SPC) are product information as approved by the Regulatory Authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising.

87. “Traditional Medicine” is the sum total of knowledge, skills, and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in

the maintenance of health as well as in prevention, diagnosis, improvement, or treatment of physical and mental illnesses.

88. "Wholesale". 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.

89. 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), is hereby 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), is hereby 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, tradition medicine, and any other products with therapeutic claims shall be a regulated under this law."

Section 8. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby 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, distribution, 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), is hereby 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), is hereby 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), is hereby amended by inserting a new section 1207 of subchapter 3 to read as follows:

"Section 1207. Pharmaceutical Unit

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:

1. Administrative Functions:

a. Administer and oversee the implementation and enforcement of this Act and regulations established under this Act;

b. Provide advice to the Secretary on matters of policies and regulations pertaining to the pharmaceutical sector, and access to pharmaceutical products;

c. Lead and coordinate the implementation of this Act and other related laws, ordinances and regulations pertaining to pharmaceutical activities and services;

d. Monitor on a regular basis the

pharmaceutical situation and generate information on access, affordability and quality, safety and efficacy of medicines;

e. Cooperate in the performance of its function in conjunction with other related established government bodies to carry out its functions"; and

f. Monitor and review the implementation of the legislation;

1. Regulatory Functions:

a. Establish the requirements and standards for the registration/marketing authorization of products and licensing of establishments based on internationally accepted standards;

b. Require that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy, and that the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell such products comply with defined standards, codes of practice and other requirements prescribed under this law, rules and regulations, administrative orders and other relevant regulations in the Federated States of Micronesia;

c. Require continued conformity of pharmaceutical products to established standards along

the supply chain until their delivery to the end user;

d. Grant, after due assessment, appraisal or evaluation, authorizations/licenses for medicinal/pharmaceutical products, whether locally manufactured or imported, and whether destined for the national market or export;

e. Cancel the authorization/registration of, or cause to be recalled from the market, such medicinal products, the continued use of which may be detrimental to public health;

f. Grant, after due assessment, appraisal or evaluation, licenses to establishments, intending to manufacture, import, export, wholesale, distribute and supply, retail or undertake any other activity in relation to pharmaceutical products;

g. Cancel the license of such establishments which do not meet requirements and standards or the continued operation of which may be detrimental to public health;

h. Maintain an inventory and publish from time to time a list of registered medicinal products and licensed establishments;

i. Ensure that dossiers for marketing authorization of medicinal products and establishments are kept up to date by the applicants and to approve

alterations/changes thereto;

j. Ensure that the promotion and marketing of medicinal products is in accordance with product information as approved by the drug regulatory authority;

k. Regulate the use of pharmaceutical products (registered & unregistered / unauthorized) for clinical trial purposes or for compassionate use;

l. Regulate the conduct and implement ethical standards and oversight of clinical trials on pharmaceutical products;

m. Monitor the presence and cause the elimination of f substandard, falsified, illegal / unlicensed pharmaceutical products in FSM;

l. Disseminate information on medicinal products to the health professions in order to promote their rational use;

n. Establish and implement a national pharmacovigilance system to monitor the safety of medicines including adverse drug reactions and events.

o. Establish and implement a system for drug recall of substandard, falsified and products that do not meet standards of quality, safety and efficacy and disseminate information on such recall;

p. Establish policy and system for post-

marketing surveillance and quality assurance of medical products along the supply chain;

q. 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; and

r. Establish other regulations or any other legal requirements that may be necessary to support the objectives of this Act.

1. Inspectoral/Inspectorate Functions:

a. Inspect all manufacturing premises, importing agents, wholesalers, distributors, hospital dispensaries, pharmacies and retail outlets to ensure compliance to rules and regulations and standards stipulated under this Act;

b. Undertake the inspection at the port of entry of all pharmaceutical products imported in the Federated States of Micronesia; and

c. Inspect unlicensed entities that are operating and conducting pharmaceutical activities, and cause the issuance of cease and decease orders as appropriate.

d. Quality Assurance Functions:

f. Establish and implement a system for post-

marketing surveillance and detection of substandard, falsified and unregistered products circulating within the jurisdiction of the Federated States of Micronesia; and

g. Provide for sampling and analytical and other testing of finished pharmaceutical products released into the distribution chain to assure their compliance with labeled specifications."

Section 13. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 4 entitled: "Regulatory Cooperation".

Section 14. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1208 of subchapter 4 to read as follows:

"Section 1208. National Drug and Therapeutics Committee

1. The Secretary shall establish a Committee to be called National Drug and Therapeutics Committee and shall be chaired by the Pharmaceutical Unit or by the Secretary's designee. This Committee and the Pharmaceutical Unit shall coordinate with each other.

2. The Committee shall:

a. Advice and assist the Secretary on policies to improve access and rational use of pharmaceutical products;

b. Establish and implement a mechanism to develop and review on a regular basis the essential medicines list and FSM Approved Medicines List;

c. Develop or adopt standard treatment guidelines and formularies that are appropriate and in consonance with the needs and services provided;

d. Establish and implement mechanisms to monitor rational drug use in all health service facilities; including monitoring of prescription, dispensing and consumption and expenditure of medicines;

e. Establish and implement antimicrobial stewardship programs in all levels of health service facilities;

f. Provide report to the Secretary on a regular basis on implementation of the above functions; and

g. Perform such other duties or functions as maybe lawfully assigned by the Secretary."

Section 15. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 5 entitled: "Regulation of Pharmaceutical Products".

Section 16. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated) is hereby amended by

inserting a new section 1210 of subchapter 5 to read as follows:

"Section 1210. 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 National Drug Therapeutic Committee 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 the National Drug Therapeutics Committee 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 17. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1211 of subchapter 5 to read as follows:

"Section 1211. Market Authorization

1. All pharmaceutical products used for the

prevention, diagnosis, treatment, management and care for medical conditions, shall be registered or granted a marketing authorization before they are imported, sold, and distributed in the Federated States of Micronesia;

2. The Secretary shall establish a registration system for pharmaceutical products. The Pharmaceutical Unit created under this Act, shall develop and implement 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 Secretary shall establish the criteria and conditions for registration, including information on the nature and characteristics of the product, pharmaceutical dosage form; quality and safety data; shelf life and storage conditions; packaging characteristics; product information approved for health professionals and the public; sales category; level of access ; name and address of manufacturer, country of manufacture; name of countries where product is registered; name and address of entity applying for the registration; source of the product; country of origin; conditions of manufacture, such other

information that are necessary to ensure the identity, source and quality and safety of the product.

4. The Secretary shall establish specific criteria and procedure for registration for new chemical entities and variations to existing marketing authorization;

5. The Secretary shall establish an expert committee, or may call upon independent experts to assist the pharmaceutical unit in the evaluation of applications for marketing authorization of pharmaceutical products.

6. The Secretary shall determine the level of fees for the evaluation of application for marketing authorizations.

7. The Secretary may limit the number of products of the same type and dosage form to be registered as well as the number of marketing authorization holders.

8. The Secretary shall promulgate the guidelines for applicants for registration or marketing authorization.

9. 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.

10. All applications shall be accompanied by certificate of pharmaceutical product (CPP)/certificate of marketing authorization in the exporting country, and certification that the product to which the certificate

applies is identical in all respects to that marketed in the exporting country, or define and justify any differences.

11. Publication of marketing authorization decisions: The Pharmaceutical unit shall publish lists of newly authorized products, including at least the following information:

a. Generic name, dosage form, and strength;

b. Brand name (if present);

c. Marketing authorization holder;

d. Product marketing authorization number; and

e. Product Profile (Indication; Safety & Efficacy Information

12. Periodic reviews: All marketing authorizations should be reviewed and updated regularly.

13. Suspension and revocation of marketing authorization: Marketing authorization may be suspended or revoked, in any of the following circumstances:

14. The product has been proven to be ineffective for the approved indication(s);

15. It is strongly suspected that the product is unsafe in the normal conditions of use;

16. The quantitative or qualitative composition is not as agreed in the marketing authorization;

17. The product is not in compliance with the

conditions of marketing authorization;

18. The product is being promoted in an inappropriate or unethical manner.

19. When the marketing authorization in the country of origin is revoked."

Section 18. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1212 of subchapter 5 to read as follows:

"Section 1212. 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. In the event of public health emergency, the Secretary shall immediately convene the National Therapeutics Committee and the Pharmaceutical Unit to determine and advice her/him on the need and urgency of the registration and importation of such pharmaceutical products;

3. The Secretary, upon the recommendation of relevant entities within the Department of Health and Social Affairs and other relevant agencies of the government shall establish the criteria of what constitutes a public health

emergency. In addition, the Secretary may refer to the advice and guidance of internationally recognized bodies and the International Health Regulations (IHR). The Secretary may authorize the entry of products and exempt these from the registration process in the following situations:

a. In the event of public health emergency;

b. Medicines urgently needed for public health programs;

c. Where severe and life-threatening illness exists, where existing registered therapy fail or are ineffective; and

e. For rare and neglected diseases

1. The use pharmaceutical products under this Section shall be placed under strict control and monitoring by the Pharmaceutical Unit."

Section 19. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1213 of subchapter 5 to read as follows:

"Section 1213. 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 20. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1214 of subchapter 5 to read as follows:

"Section 1214. 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 1210 of this Act."

Section 21. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by

creating a new subchapter 6 entitled: “Quality Assurance”.

Section 22. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated). is hereby amended by inserting a new section 1215 of subchapter 6 to read as follows:

“Section 1215: 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.

3. When resources allow, the Secretary shall cause the establishment and operation of a national pharmaceutical control laboratory to carry out the required analysis and tests to ensure that pharmaceutical products meet quality specifications.”

Section 23. 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 Medicine”.

“Section 1216. Importation of Medicines

1. Only medicines included in the FSM Approved List and issued marketing authorization 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, marketing authorization, certificate of pharmaceutical product and certificates of analysis and shall be inspected upon arrival at the port-of-entry and in the establishments 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 24. Chapter 12 of title 41 of the Code of the

Federated States of Micronesia (Annotated), is hereby 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) is hereby amended by inserting a new section 1217 of subchapter 8 to read as follows:

"Section 1217. 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.

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 marketing authorization in FSM.

3. The Secretary may from time to time order the sampling of products at the port of entry for quality testing.

4. The Secretary may cause the non-release of pharmaceutical product, with questionable nature and origin and when risk of these being substandard or falsified exists. Pharmaceutical products that are 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) is hereby amended by creating a new subchapter 9 entitled: "Labeling, Packaging, Advertisement or Promotion".

Section 27. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated) is hereby amended by inserting a new section 1218 of subchapter 9 to read as follows:

"Section 1218. 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 for use.

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 28. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated) is hereby amended by creating a new subchapter 10 entitled: "Medicine Information".

Section 29. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by

inserting a new section 1219 of subchapter 10 to read as follows:

"Section 1219: Medicine Information

1. Licensed dispensers or sellers of medicines are required to provide adequate information and appropriate patient counseling at all times when a medicine is dispensed or sold.

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."

Section 30. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 11 entitled: "Pharmacovigilance".

Section 31. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1220 of subchapter 11 to read as follows:

"Section 1220: Pharmacovigilance

1. The Secretary shall establish the national pharmacovigilance system to monitor and report adverse events, adverse drug reactions and adverse events following immunizations (AEFI) and other such conditions to safe guard public health, aid in the regulation of

pharmaceutical products; Such information collected shall be shared with relevant authorities, health service providers, health professionals, and when necessary to the public in a timely manner.

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 Pharmaceutical Unit the nature of such effects and the circumstances in which they arose."

Section 32. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 12 entitled: "Recall and Withdrawal".

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 1220 of subchapter 12 to read as follows:

"Section 1221: Recall and Withdrawal

1. The Secretary shall establish a system for medicine recall and withdrawal of:

a. Substandard, falsified and unlicensed/unregistered medicines;

b. Pharmaceutical products that are imported, distributed and sold by establishments which are not licensed to conduct pharmaceutical activities in the Federated States of Micronesia;

c. Products with therapeutic claims that are not otherwise registered as pharmaceutical products;

d. Secretary shall ensure that Information on such recalls are disseminated to the public, and reported to international monitoring bodies in the case of substandard and falsified products."

Section 34. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 13 entitled: "Antimicrobial Medicines".

Section 35. 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 13 to read as follows:

"Section 1222: Antimicrobial Medicines

1. In addition to the regulations established under this Act, the importation, distribution, sale, prescription, dispensing and use of antimicrobial drugs shall be placed under the strict regulation and oversight by the Secretary.

2. The Secretary shall direct the stringent monitoring of prescription, dispensing, sale and use of antimicrobial medicines in all pharmaceutical establishments and across all levels of health care;

3. The Secretary shall require from time to time the collection of samples and testing of antimicrobials in a competent laboratory

4. The Secretary shall direct the establishment of antimicrobial stewardship programs at all levels of health care,

5. The Secretary shall coordinate with all relevant departments the restriction and monitoring of use of antibiotics in the agriculture and animal sectors including the use of antimicrobials for other purposes other than for their intended use under this Act.

6. It shall be unlawful to use antimicrobials without the direction, advice of competent professionals and outside of their intended use."

Section 36. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by creating a new subchapter 14 entitled: "Establishments".

Section 37. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1223 of subchapter 14 to read as follows:

"Section 1223: 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 38. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1224 of subchapter 14 to read as follows:

"Section 1224: 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 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. All fees shall be deposited in an account nominated by the Secretary as a

revolving fund for the Unit or the Department of Health and Social Affairs purposes."

Section 39. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended to insert a new section 1225 of subchapter 14 to read as follows:

"Section 1225. 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 40. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended to insert a new section 1226 of subchapter 14 to read as follows:

"Section 1226. 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 41. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated) is hereby amended to insert a new section 1227 of subchapter 14 to read as follows:

"Section 1227. 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 42. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new subchapter 15 entitled: "Manufacturing".

Section 43. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1228 of subchapter 15 to read as follows:

"Section 1228. Unless permitted by the Secretary, applicable legislation, health policy and regulation, the manufacturing of medicines is prohibited".

Section 44. Chapter 12 of title 41 of the Code of the

Federated States of Micronesia (Annotated) is hereby amended by inserting a new subchapter 16 entitled: "Internet Pharmacy"

Section 45. Chapter 12 of title 41 of the Code of the Federated States of Micronesia is hereby amended by inserting a new section 1229 of subchapter 16 to read as follows:

"Section 1229. Unless permitted by the Secretary, applicable or relevant legislations, national health policies and regulations, Internet Pharmacy is strictly prohibited."

Section 46. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new subchapter 17 entitled: "Complementary and Traditional Medicines".

Section 47. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1230 of subchapter 17 to read as follows:

"Section 1230. 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 48. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1231 of subchapter 17 to read as

follows:

"Section 1231. Traditional Medicine

The Secretary shall promote and regulate the use of traditional medicine through regulation to be promulgated in accordance with the Administrative Procedures Act in Title 17 of this Code."

Section 49. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new subchapter 18 entitled: "General Offenses and Penalties".

Section 50. Chapter 12 of title 41 of the Code of the Federated States of Micronesia (Annotated), is hereby amended by inserting a new section 1233 of subchapter 18 to read as follows:

"Section 1233. Penalties

1. Any wilful 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.

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

Section 51. 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: 5/22/18 Introduced by: /s/ Florencio S. Harper
Florencio S. Harper
(by request)