EDDIE BAZA CALVO
Governor

RAY TENORIO
Lieutenant Governor

Office of the Governor Of Guam

OCT 17 2017

Honorable Benjamin J.F. Cruz
Speaker
I Mina'trentai Kuåttro Na Liheslaturan Guåhan
Guam Congress Building
163 Chalan Santo Papa
Hagåtña, Guam 96910

GH 34-17-1121
Speaker Benjamin J.F. Cruz
OCT 23 2017
Time: 1232 [ ] AM [/] PM File No. 34-1060
Received By:

Via: Secretary of the Legislature
The Honorable Regine Biscoe Lee

2017 OCT 23 PM 12:48

Dear Mr. Speaker:

Hafa Adai! Enclosed is the proposed *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances* which this office transmits to *I Liheslaturan Guåhan* pursuant to the Administrative Adjudication Law (AAL). As required in the AAL, the Division of Environmental Health (DEH) of the Department of Public Health and Social Services held a public hearing to receive public comments on the proposed rules and regulations on June 26, 2015.

The proposed *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances* was also posted to the website of the Department of Public Health and Social Services (www.dphss.guam.gov) on June 12, 2015, accompanied with a press release seeking public comments. Five copies of the proposed rules were on file at DEH during that time.

No Economic Impact Statement was prepared for these proposed rules and regulations because the impact to the general public will be less than $500,000. The determination of economic impact is strictly confined to the implementation of these regulations, and does not include any regulatory, policy, or operational requirements relevant to the implementation of the *Rules and Regulations Governing Joaquin (KC) Concepcion Compassionate Cannabis Use Act of 2013*.

The announcements for the June 26, 2015 public hearing were printed in the Marianas Variety on June 12, 2015 and June 25, 2015 (copies enclosed). No members of the public attended the hearing, and no written testimony was received by DEH after the public hearing. The minutes of the public hearing is also attached.

The proposed draft was submitted for review to the Office of the Attorney General on August 07, 2015. Approval as to form of the proposed rules and regulation was received by DPHSS on September 22, 2017 (copy enclosed). The formatting of these proposed rules is in conformance to the Compiler of Laws' *Guidance for Formatting Rules and Regulations (GAR)* (dated April 22, 2013) document.

We have enclosed the following materials for your reference:

1. A copy of the public hearing notice that was printed in the Marianas Variety on June 12, 2015 and June 25, 2015;
2. A copy and a duplicate of the draft proposed *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances*, as well as an electronic copy;
3. A copy of the memo of approval from the Office of the Attorney General;
4. Minutes of the June 26, 2015 public hearing; and
5. Recording of the June 26, 2015 public hearing.

Should you have any questions regarding this matter, please contact Mr. James W. Gillan, the Director of the Department of Public Health and Social Services, at 735-7101.

Senseramente,

EDDIE BAZA CALVO

Enclosures

Cc: Dir Chrono
DEH Chrono
BCI Copy
CSP Copy

PUBLIC HEARING NOTICE PRINTED IN THE MARIANAS VARIETY GUAM EDITION ON JUNE 12, 2015, AND JUNE 25, 2015

Exxon Mobil halts 3 platforms

After oil spill crippled pipeline

LOS ANGELES (AP) – The shutdown of a pipeline that spilled up to 101,000 gallons of crude on the Santa Barbara coast forced Exxon Mobil Corp. to halt operations at three offshore platforms because it couldn't deliver oil to refineries, the company said Tuesday.

The company temporarily ceased operations last week because Santa Barbara County rejected its emergency application to truck oil to refineries, spokesman Richard Keil said.

A Santa Barbara County official said the company's problem did not constitute an emergency and it could go through the normal procedure, which requires extensive environmental review, to get a permit to truck the oil.

The shutdown is not expected to have an impact on oil prices, but it does harm Exxon Mobil's bottom line even though production from the platforms is small compared to the company's overall output, said Tom Kloza, global head of energy at the Oil Price Information Service.



In this May 21 file photo, an oil-covered bird flaps its wings amid oil at Refugio State Beach, north of Goleta and the Gaviota Plains All American Pipeline. The shutdown of the pipeline that spilled up to 101,000 gallons of crude on the Santa Barbara coast forced Exxon Mobil Corp. to halt operations at three offshore platforms. AP

Crude was selling last week for $60 to $64 a barrel and could fetch more than $90 when refined for automobile gas, he said. That provided a lot of incentive for Exxon Mobil.

"I'm sure it's a royal pain for them," Kloza said. "Given the profit margins for gasoline, whether you have to (deliver) it by wheelbarrow or rickshaw, you're very motivated."

Exxon Mobil had cut production from the rigs by two-thirds after Plains All American Pipeline's conduit was shut down by a May 19 spill that soiled pristine coastline and spread tar balls as far as Los Angeles County, some 100 miles away. Nearly 200 birds and more than 100 marine mammals have been found dead in the waters.

Federal regulators investigating the cause of the spill have revealed the 2-foot-wide pipe was severely corroded where it ruptured but have not issued any findings or penalties.

The pipeline carried oil to refineries from an Exxon Mobil facility in Las Flores Canyon that separates crude, water and natural gas about 15 miles west of Santa Barbara.

Before the shutdown, daily production from the Hondo, Harmony and Heritage rigs that sit 5 to 8 miles offshore had been cut from 50,000 barrels to 10,000 barrels. The production is just a sliver of the more than 4 million barrels per day Exxon Mobil reported in the first quarter of the year. There are 42 gallons in a barrel.

Senate vote moves Obama's trade agenda to brink of enactment

WASHINGTON (AP) – President Barack Obama's long-pursued trade agenda took a giant step toward becoming law on Tuesday, and opponents grudgingly conceded they now must fight on less-favorable terrain.

A key Senate vote greatly brightened Obama's hopes for a 12-nation Pacific-rim trade agreement, a keystone of his effort to expand U.S. influence in Asia. The trade pact would be a high point in a foreign policy that has otherwise been consumed by crisis management, and would give Obama a rare legislative achievement in the Republican-controlled Congress.

The Senate voted 60-37 to advance his bid for "fast track" negotiating authority. That was the minimum number of votes needed on the procedural question. But final passage, expected no later than Wednesday, needs only a simple majority, which would let Obama sign fast track into law.

The president also wants to continue a retraining program for workers displaced by international trade. House and Senate support appears adequate, but even if that measure stumbles, the long-coveted fast track bill will be on Obama's desk.

"This is a very important day for our country," Senate Majority Leader Mitch McConnell, R-Ky., said. In the strange-bedfellows politics of trade, he was among the Republican congressional leaders vital in pushing the agenda forward, with only modest help from Democrats.

Opposed

The big majority of Democrats, especially in the House, oppose free-trade agreements, as do the labor unions that play important roles in Democratic primaries. They say free-trade agreements ship U.S. jobs overseas.

Obama, major corporate groups, GOP leaders and others say U.S. products must reach more global markets. They say anti-trade forces have exaggerated the harm done by the 1994 North America Free Trade Agreement, or NAFTA.

Previous presidents have enjoyed fast track authority. It lets them propose trade pacts that Congress can reject or ratify, but not change or filibuster.

Obama wants to complete negotiations for the 12-nation Trans-Pacific Partnership, or TPP. Members include Japan, Mexico and Canada.

He would ask Congress to ratify it, following weeks or months of public scrutiny that will give opponents another shot.

Several such organizations said they will regroup and fight on.

Fast track

The liberal group MoveOn.org said fast track "puts the interests of massive, multinational corporations over those of American workers, consumers, and voters." When the Pacific-rim proposal becomes public, the group said, "MoveOn members and our allies nationwide will hold our elected officials accountable and urge them to vote down any deal that's bad for the American economy."

Contractor's credential used to breach system

WASHINGTON (AP) – The head of the government agency that suffered two massive cyberattacks said Tuesday that a hacker gained access to its records with a credential used by a federal contractor.

Despite calls for her ouster, the director of the Office of Personnel Management said if anyone is responsible for the breaches, it's the hackers.

Katherine Archuleta told a Senate hearing that old computer networks were to blame for the cyberbreak-ins that exposed private information on nearly every federal employee and personal histories of millions with security clearances.

"If there is anyone to blame, it's the perpetrators," she said.

Sen. John Boozman, R-Ark., the chairman of the Senate Appropriations Committee panel where she testified, said OPM officials are blaming antiquated systems, but not all the breaches occurred exclusively on older networks.



"I still don't think we know exactly what's gone on," Boozman said later in the afternoon on his way out of a classified briefing on cybersecurity.

Archuleta told a House oversight committee last week that many of the agency's systems were too old to support encryption, which would have made the data harder to steal. But the agency's independent watchdog is challenging that assessment in written testimony to be delivered Wednesday to the same committee.

OPM Inspector General Patrick McFarland says some of the systems involved in the data breach were modern, so encryption could have been used.

GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
NOTICE OF PUBLIC HEARING
PURSUANT TO 5 GCA, DIVISION 1, CHAPTER 5 TITLE 5 GCA, ALL AGENCIES OF THE GOVERNMENT OF GUAM ARE REQUIRED TO PUBLISH A NOTICE OF PUBLIC HEARING ON THE ADOPTION, PROMULGATION, REPEAL/ RECISSION, OR AMENDMENT OF RULES. THE DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES WILL BE ACCEPTING PUBLIC COMMENTS ON THE PROMULGATION OF RULES AND REGULATIONS GOVERNING THE ISSUANCE OF THE FOLLOWING:
SANITARY PERMIT (CHRP P.M.)
GUAM CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE (H.38 P.M.)
DATE: Friday, June 26, 2015
TIME: 3:00 P.M. TO 5:00 P.M.
PLACE: PHCC CONFERENCE ROOM, CENTRAL PUBLIC HEALTH FACILITY, MANGILAO
Copies of the proposed rules and regulations are available for inspection at the Division of Environmental Health (DEH) on the 2nd floor of the Department of Public Health and Social Services in Mangilao, and on the DPHSS webpage at dphss.guam.gov. Please call DEH at 735-7221 for questions and assistance.
/s/ JAMES W. GILLAN
Director, Department of Public Health and Social Services

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Shipping carriers to pay invasive species inspection fees

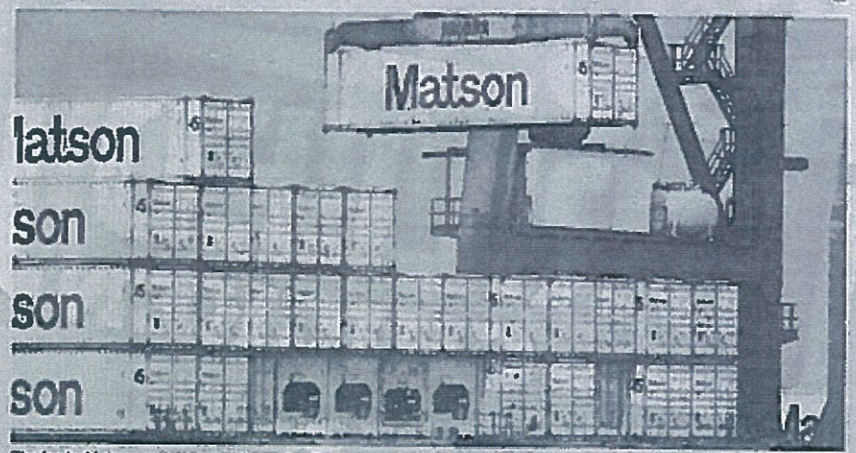
By Jasmine Stole
jasmine@mvguam.com
Variety News Staff

THE Department of Agriculture will soon implement an invasive species inspection fee to "prepare for the implementation of requirements" of Guam law established in 2014.

According to a memo from Department of Agriculture acting Director Matthew Sablan, collections for invasive species inspection fees will apply to all maritime transportation companies beginning July 1. The memo was sent to companies last month on May 17.

Maritime companies will make deposits at least on a monthly basis to the government, according to the memo.

Matson Inc. also informed its customers of the extra fees last month. Because of the new fees from the Department of Agriculture, Matson customers can expect to see an increase in their freight charges. Matson officials said in a memo to customers. The fee for Matson customers will depend on the gross weight of total shipments.



The fee for Matson customers will depend on the gross weight of total shipments, according to the Matson memo. Variety file photo

According to the law, for every 1,000 pounds of freight brought to Guam, 75 cents will be charged to the person responsible for paying the freight charges.

For example, for a 38,000-pound total gross weight shipment, an additional $28.87 will be charged to Matson customers for the inspection fee.

The fees will be deposited into the Guam's Invasive Species Inspection Fee Fund.

According to Guam law, the fee is for inspections, quarantine and eradicating invasive species contained in foreign or domestic marine commercial shipments and it applies to all cargo imported to Guam.

Sablan said yesterday the fees are necessary to develop biosecurity measures.

According to the law, companies or individuals who do not pay the invasive species inspection fee have 45 days to pay the original fees and an additional fee that is either twice the original payment amount or $50, whichever is greater.

Certain items are exempt from the imported freight fee including bulk sand, quarried product freight, cement, coal and liquid shipped in bulk.

GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
DIPATTAMENTUN SALUT PUBLIKO YAN SETBISION SUSIAT
123 Chalan Kareta Mangilao, Guam 96913-6304

NOTICE OF PUBLIC HEARING

PURSUANT TO § 9301, DIVISION 1, CHAPTER 9 TITLE 5 GCA, ALL AGENCIES OF THE GOVERNMENT OF GUAM ARE REQUIRED TO PUBLISH A NOTICE OF PUBLIC HEARING ON THE ADOPTION, PROMULGATION, REPEAL, RECISSION, OR AMENDMENT OF RULES. THE DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES WILL BE ACCEPTING PUBLIC COMMENTS ON THE PROMULGATION OF RULES AND REGULATIONS GOVERNING THE ISSUANCE OF THE FOLLOWING:

SANITARY PERMIT (3:00 P.M.)
GUAM CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE (4:30 P.M.)

DATE: Friday, June 26, 2015
TIME: 3:00 P.M./TO 6:00 P.M.
PLACE: PHCC CONFERENCE ROOM, CENTRAL PUBLIC HEALTH FACILITY, MANGILAO

Copies of the proposed rules and regulations are available for inspection at the Division of Environmental Health (DEH) on the 2nd floor of the Department of Public Health and Social Services in Mangilao, and on the DPHSS webpage at dphss.guam.gov. Please call DEH at 735-7221 for questions and assistance.

/s/ JAMES W. GILLAN
Director, Department of Public Health and Social Services

GFD ends search for fisherman



Doc. No. 34GL-17-1121.

26 GAR - PUBLIC HEALTH & SOCIAL SERVICES

DIV. 1 - DIRECTOR OF PUBLIC HEALTH & SOCIAL SERVICES

RULES GOVERNING THE MANUFACTURE, DISTRIBUTION, AND DISPENSING OF CONTROLLED SUBSTANCES

DIVISION OF ENVIRONMENTAL HEALTH
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
123 CHALAN KARETA
MANGILAO, GUAM 96910-6304

Adopted pursuant to the Administrative Adjudication Law
Public Hearing: June 26, 2015
Submitted to Legislature:
Effective Date:

ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000.00) annually. As provided in § 9301(i) of Title 5 GCA, Chapter 9, Article 3, an economic impact statement is not required for these proposed rules.

"**Article 16**

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§41601. Purpose.

The purpose of these rules is to regulate the lawful manufacture, distribution, and dispensing of controlled substances through registration and control to prevent the diversion of legitimately produced controlled substances into illegitimate channels.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (i.e., inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion.

These rules do not provide a comprehensive, regulated framework for providing medical cannabis to individuals, in which the Joaquin (KC) Concepcion II Compassionate Cannabis Use Act of 2013 identifies nine (9) debilitating medical conditions for which a patient may receive medical cannabis. These rules also do not regulate practitioners, patients and organizations that participate in the medical cannabis system, nor does it establish specific standards and procedures for registering medical cannabis patients, designated caregivers, physicians for humans, producers, and dispensaries to protect the health, safety, and welfare of the residents and patients of Guam, by prescribing the manner in which medical cannabis is regulated. Nothing in these rules and regulations is intended to address any matters related to requiring a physician to certify the use of medical cannabis for a patient; require the accommodation or protection for any employee for the medical use of cannabis in any place of employment; any matters involving banking and financial services of a medical cannabis facility or business; any matters involving local or federal law enforcement actions; or any matters involving the medical use of cannabis by an immigrant or foreign national. The Department or its employees shall not be liable for any deleterious outcomes

from the medical use of cannabis by any patient, or from an individual's participation as a caregiver, employee or physician, or from the operation of a cannabis dispensary, cultivation site, or laboratory.

§41602. Authority.

Section 67.301 of P.L. 24-149, an Act to Repeal and Reenact Chapter 67 of Title 9, Guam Code Annotated, authorizes the Director to promulgate rules providing for the registration and control of the manufacture, distribution, and dispensing of controlled substances within Guam.

§41603. Title.

These rules and regulations shall be known and cited as the *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances* or the *Rules for Pharmaceutical Controlled Substances.*

§41604. Definitions.

As used in these rules:

(a) *'Act'* shall mean P.L. 24-149, an Act to Repeal and Reenact Chapter 67, Title 9, Guam Code Annotated, which is also known as the Uniform Controlled Substances Act.

(b) *'Cannabis'* or *'Marijuana' or "Marihuana'* means all parts of the plant of the genus *Cannabis sp.*, whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed, or its resin, including marijuana concentrate. *Cannabis sp.* does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other products.

(c) *'CSR'* shall mean the Guam Controlled Substances Registration issued by the Department.

(d) *'DEA'* shall mean the United States Drug Enforcement Administration.

(e) *'Department'* or *'DPHSS'* shall mean the Department of Public Health and Social Services.

(f) *'Director'* shall mean the Director of the Department of Public Health and Social Services, or his designee.

(g) *'Dispense'* means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(h) *'Distribute'* means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(i) *'Individual registrant'* shall mean a physician, dentist, veterinarian, podiatrist or other lawfully licensed person permitted on Guam to dispense controlled substances in the course of his professional practice, but does not include an institutional registrant, a pharmacy, or a pharmacist.

(j) *'Institutional registrant'* shall mean a hospital, clinic, or other lawfully licensed establishment wherein dispensing of controlled substances are permitted by Guam in the course of that establishment's business, but does not include a pharmacy.

(k) *'Manufacture'* means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(l) *'Pharmacist'* means any pharmacist licensed by the Department of Public Health and Social Services' Health Professional Licensing Office to dispense controlled substances and shall include any other person (e.g. pharmacist intern) authorized by the Department of Public Health and Social Services' Health Professional Licensing Office to prescribe, dispense or store controlled substances under the supervision of a pharmacist licensed by Department of Public Health and Social Services' Health Professional Licensing Office.

(m) *'Pharmacy'* shall mean a lawfully licensed pharmacy permitted on Guam to dispense controlled substances in the course of that establishment's business.

(n) *'Practitioner'* means a physician, dentist, veterinarian, scientific investigator, pharmacist, pharmacy, hospital, government operated or government contracted animal shelter, or other person licensed, registered, or otherwise permitted, by Guam, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(o) *'Registrant'* shall mean any person or establishment registered pursuant to the Guam Uniform Controlled Substances Act.

(p) *'Regulated person'* means a person who manufactures, distributes, dispensed, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for a transaction involving a listed chemical, a tableting machine, or an encapsulating machine (including doing business as a Reverse Distributor or Reverse Processor).

(q) *'Reverse distributor'* or *'Reverse processor'* means a person who receives controlled substances acquired from another Drug Enforcement Administration and CSR registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.

Unless otherwise stated in these rules, the definitions in the Act shall also be the definitions of these rules.

§41605. Guam Controlled Substances Registration.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any listed chemical compound contained in the controlled substances listing or any controlled substance other than Cannabis and Cannabis products, or who owns and operates a tableting machine, an encapsulating machine or who acts as a broker or trader for an transaction involving a listed chemical, a tableting machine, or an encapsulating machine (including doing business as a reverse distributor or reverse processor) shall annually obtain a Guam Controlled Substances Registration unless exempted by law or as otherwise exempted by these rules. Only persons or institutions directly engaged in such activities are required to obtain a registration. (For example, a

stockholder or parent corporation of a corporation manufacturing controlled substances are not considered directly engaged in such activities, and need not be registered.)

(b) A practitioner must be registered with DPHSS before dispensing a controlled substance or conducting research with respect to a controlled substance included in Schedules II through V. DPHSS need not require separate registration under this Article for a practitioner engaging in research with non-narcotic substances included in Schedules II through V if the registrant is already registered under this Act in another capacity, or if the practitioner is already legally registered in Guam to dispense or conduct research on Cannabis. A practitioner registered under Federal law to conduct research with a substance included in Schedule I may conduct research with the substance in Guam upon furnishing DPHSS evidence of the Federal registration.

(c) A reverse distributor or reverse processor must be registered with DEA and DPHSS before receiving controlled substances acquired from another DEA and CSR registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or where necessary, processing such substances or arranging for processing such substances for disposal.

(1) The registration and other requirements for reverse distributors or reverse processors shall be the same as those currently imposed on distributors, to include but not limited to, accountability, security, inventory, recordkeeping, and reporting requirements.

(d) Upon approval by DPHSS, the registrant shall receive a Guam Controlled Substances Registration certificate that shall state:

(1) Name of the registrant;

(2) Controlled substance schedules the registrant is authorized to handle;

(3) Physical location of the principal place of business/practice, and mailing address if different from the physical address;

(4) Guam Controlled Substances Registration number, as provided by DPHSS, and its expiration date;

(5) Signature of the Director; and

(6) Other applicable information determined by the Director.

(e) Registrant shall post the Guam CSR certificate at the physical location of practice or business where an authorized inspector, as designated by DPHSS, will be able to inspect the certificate.

(f) The Director may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest.

§41606. Separate Registrations for Separate Locations, and Transfer of Locations.

(a) A separate registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed by a person or business.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed.

(1) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised, but which neither contains such substances nor serves as a distribution point for filling sales orders; and

(2) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise

dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained; and

(3) A warehouse where controlled substances are stored by or on behalf of the registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to a person not required to register by virtue of the Guam Uniform Controlled Substances Act.

(c) A registrant who intends to move his place of practice or business must request a modification of his Guam CSR certificate. The request must be made in writing and approved prior to the effective date of the move. If any registrant moves his place of business or practice without requesting and obtaining prior approval in the form of a modification of his Guam CSR certificate by DPHSS, then his registration shall automatically become invalid regardless of the expiration date.

§41607. Application.

(a) Any practitioner who is required to be registered and who is not so registered may apply for registration at any time. No practitioner required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a CSR is issued by the Director to such person.

(b) Interested persons may pick up the application for CSR at the Division of Environmental Health of DPHSS or may request the application to be mailed.

(c) The application shall state the following:

(1) Name of applicant;

(2) Name of business or practice;

(3) Physical and mailing address of business or practice;

(4) Telephone and facsimile numbers;

(5) Schedule(s) of controlled substances utilized;

(6) Licensed profession; and

(7) Any other information, or materials, deemed necessary by DPHSS, including but not limited to, any surrender, suspension, or revocation of controlled substances privileges from the DEA or DPHSS, or from any other state or federal agency, and any conviction record involving any controlled substances at any time and under any law governing the same.

(d) Renewal application for CSR will be mailed to the address indicated on the registrant's last application at least sixty (60) days prior to the date of expiration. Any registrant not receiving the renewal application 45 days prior to date of expiration should immediately notify DPHSS.

(f) Any person who is registered may apply for a renewal, provided it is not more than 60 days from the expiration date stated on his CSR.

(g) Any person applying for a renewal after 30 days or more from the expiration date stated on his CSR shall be considered a new applicant.

§41608. Filing of Application.

(a) All applications shall be delivered to the Division of Environmental Health of the Department of Public Health in Mangilao or mailed to the Division of Environmental Health, the Department of Public Health and Social Services, 123 Chalan Kareta Mangilao, Guam 96913-

6304.

(b) The post-marked date shall be considered the date of receipt by DPHSS for all applications received by mail. The date of acknowledged payment for application shall be considered the date of receipt by DPHSS for all other applications not received by mail.

(c) Only the original, complete application with appropriate payment shall be accepted and processed. Any photocopy, incomplete or illegible application, or any application not written in indelible ink, or missing a required document or payment, shall not be processed and shall be returned via mail.

§41609. Additional Information.

(a) DPHSS may require an applicant to submit such documents or written statements of fact as DPHSS deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within ten working days after being requested to do so shall be deemed a waiver by the applicant to present such documents or facts for consideration by DPHSS in granting or denying the application.

(b) All registrants applying for the Guam Controlled Substances Registration with DPHSS, or already registered with DPHSS, must provide a copy of their most recent DEA Controlled Substances Registration Certificate (federal registration) once that certificate becomes available to the registrant.

§41610. Amendments to and Withdrawals of Applications.

An application may be amended or withdrawn without permission of DPHSS at any time before the applicant receives an order to show cause pursuant to the Act. An application may be amended or withdrawn as a matter of course due to a change in the applicant's federal controlled

substances status or registration.

§41611. Fee Amounts.

(a) For each initial Controlled Substances Registration:

(1) To manufacture controlled substances, the applicant shall pay a fee of **One Thousand Dollars ($1000).**

(2) To distribute controlled substances, the applicant shall pay a fee of **Five Hundred Dollars ($500).**

(3) To dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants shall pay a fee of **Five Hundred Dollars ($500)**, and a pharmacy shall pay a fee of **Five Hundred Dollars ($500).**

(b) For each renewal of Controlled Substances Registration:

(1) To manufacture controlled substances, the registrant shall pay fee of **One Thousand Dollars ($1000).**

(2) To distribute controlled substances, the registrant shall pay fee of **Five Hundred Dollars ($500).**

(3) For each renewal registration to dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants shall pay a fee of **Five Hundred Dollars ($500)**, and pharmacy shall pay a fee of **Five Hundred Dollars ($500).**

(c) Any registrant who submits its renewal application thirty days after the expiration date shall be considered a new applicant and shall pay the required initial fee.

(d) Any registrant who has a current CSR and is required to correct or update such CSR due to change of address or any other reasons requiring the re-issuance of another CSR, shall pay a fee of Ten Dollars ($10.00).

(e) Registration and renewal fees shall be paid at the time when application for registration or renewal is submitted for filing. Payment shall be made in the form of a certified or cashier's check, money order, or personal or business check drawn through a locally existing bank. Initial application and renewal application fees are non-refundable.

§41612. Persons Exempt from Fee.

(a) Department of Public Health and Social Services shall exempt from payment of a fee for registration or renewal any official, employee, or entity of DPHSS who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense such substances, to conduct research and instructional activities or chemical analysis with such substances or any combination thereof in the course of his or its official duties or employment.

(b) Department of Public Health and Social Services shall exempt from payment of a fee for registration or renewal any official, employee, or entity of a law enforcement agency laboratory, including laboratories of the DEA, which is authorized to obtain and transfer controlled substances for use as standards in chemical analysis, Guam Police Forensic Laboratory, who or which is authorized under the Attorney General of Guam or the Judiciary of Guam to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this subchapter. The Attorney General of Guam may authorize an official, employee, or entity to

possess controlled substances, by obtaining such substances from investigations, examination of scenes of crime, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court, and to conduct research or chemical analysis with such substances or any combination thereof in the course of his or its official duties or employment. Such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration.

(c) In order to claim exemption from payment of a registration or renewal fee, the registrant shall submit a statement wherein the registrant's supervising officer certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or otherwise be permitted to handle controlled substances.

(d) Exemption from payment of a registration or renewal fee does not exempt the registrant from any other requirements or duties prescribed by law.

§41613. Exemption of Agents and Employees; Affiliated Practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment.

(b) Practitioner (including an intern, resident or foreign physician) who is an employee of a registered hospital or clinic may dispense controlled substances under that hospital's or clinic's registration provided that:

(1) Such dispensing is done in the usual course of his professional practice as an employee of the institution;

(2) Such employed practitioner is authorized or permitted to do so by the laws of Guam;

(3) The hospital or the institution has verified that the practitioner is so permitted to dispense, administer, or prescribe controlled substances in Guam;

(4) Such practitioner is acting only within the scope of his employment in the hospital or institution;

(5) The hospital or the institution authorizes the practitioner to dispense under the institution's registration and designates a specific internal code number for each practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the hospital's or institution's Guam CSR number, preceded by a hyphen (ex: HOO1-01 or COO1-A1); and

(6) The hospital or the institution provides a current list of internal codes with corresponding individual practitioners to DPHSS, and is made available at all times to pharmacies registered with the Department and law enforcement agencies upon request for the purpose of verifying the authority of the administering, dispensing, and prescribing practitioner.

§41614. Exemption of Certain Military and Other Personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, U.S. Navy, U.S. Marine Corp., U.S. Air Force, U.S. Coast Guard, and U.S. Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase controlled substances in the course of his official duties. Prescriptions written by persons mentioned in this section may be honored by a pharmacy outside the military installation, if so

desired by the pharmacist, provided that:

(1) Pharmacist makes a reasonable effort to determine that the prescription is legitimate, which may include a call back to the prescriber, and/or other good faith efforts to insure the identity; and

(2) The prescription has the branch of service/agency, service identification of practitioner, practitioner's and patient's name and address, date, and instructions.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities and pay the required fee.

§41615. Exemption of Law Enforcement Officials.

(a) The requirement of registration is waived for the following persons in circumstances described in this section:

(1) Any officer or employee of a Government of Guam agency who is engaged in the enforcement of any Guam law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(2) Any officer or employee of the United States DEA, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties, including personnel in the investigative services of the military forces stationed on Guam.

(3) Any officer or employee of Guam, or any political subdivision or agency

thereof, who is engaged in the enforcement of any Guam law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.

(4) Any official exempted by this section may, when acting in the course of his official duties, possess a controlled substance and distribute such substance to any other official exempted by this section and acting in the course of his official duties.

(5) Any official exempted by this section may procure a controlled substance in the course of an inspection, in accordance with the Act, or in the course of any criminal investigation involving the person from whom the substance was procured.

(6) In order to enable law enforcement agency laboratories, including laboratories of the DEA, to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in section 515(d) of the federal Controlled Substances Act (21 U.S.C. 885(d)). For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

(7) In addition to the activities authorized under a registration to conduct chemical analysis pursuant to Title 21 of the Code of Federal Regulations, Part 1301, §1301.13(e)(1)(ix), laboratories of the DEA shall be authorized to manufacture or import controlled substances for any lawful purpose, to distribute or export such substances to any

person, and to import and export such substances in emergencies without regard to the requirements of Title 21 of the Code of Federal Regulations, Part 1312 if a report concerning the importation or exportation is made to the Drug Operations Section of the DEA within 30 days of such importation or exportation.

§41616. Exemption of Civil Defense Officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is in accordance with applicable local and federal laws governing controlled substances and any emergency preparedness plans of Civil Defense.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization within his jurisdiction proclaimed by the Governor or by a concurrent resolution of the Guam Legislature or by the Civil Defense network on Guam, which official, in the course of his official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on the official form provided by Civil Defense.

(c) Such forms may be used and are valid only during a state of emergency or disaster in which the organization using such forms has civil defense or disaster relief

jurisdiction, and which shall state the position of the user and the nature and legal designation of the emergency or disaster. Any person registered under the Act may complete such forms. The organization using civil defense emergency order forms will be deemed to be registered under the Act for purposes of record keeping.

§41617. Administrative Review Generally.

DPHSS may inspect or cause to be inspected the establishment of an applicant or registrant, pursuant to the Act. DPHSS shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of the Act have been met by the applicant.

§41618. Certificate of Registration.

DPHSS shall issue a certificate of registration to an applicant if the issuance of registration or renewal is required under the applicable provisions of the Act. In the event that the issuance of registration or renewal is not appropriate, DPHSS shall deny or refuse the application. Before denying or refusing any application, DPHSS shall issue an order to show cause pursuant to these rules. If requested by the applicant, DPHSS shall hold a hearing on the application pursuant to these rules and the Administrative Adjudication Law.

§41619. Suspension or Revocation of Registration.

(a) DPHSS may suspend any registration pursuant to the Act for any reasonable and justifiable period of time as determined by DPHSS.

(b) DPHSS may revoke any registration pursuant to the Act.

(c) Before revoking or suspending any registration, DPHSS shall issue an order to show cause pursuant to the Act and, if requested by the registrant, shall hold a hearing pursuant to

the Act and the Administrative Adjudication Law. Notwithstanding the requirements of this section, however, DPHSS may suspend any registration pending a final order pursuant to these rules.

(d) Upon service of the order of DPHSS suspending or revoking registration, the registrant shall immediately surrender his certificate of registration to DPHSS. In addition, the registrant, as instructed by DPHSS, shall deliver all controlled substances in his possession to DPHSS for destruction.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by such revocation or suspension. No fees shall be required to be paid for the new certificate. The registrant shall surrender the old certificate of registration to DPHSS. In addition, the registrant shall, as instructed by DPHSS, deliver to DPHSS, or to authorized agents, all of the particular controlled substance or substances affected by the revocation or suspension that are in his possession for destruction.

§41620. Suspension of Registration Pending Final Order.

(a) DPHSS may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where DPHSS finds that there is an imminent danger to the public health or safety. If DPHSS so suspends, DPHSS shall serve with the order to show cause pursuant to the Act an order of immediate suspension which shall contain the statement of DPHSS' findings regarding the danger to the public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly

surrender his certificate of registration to DPHSS. Also, upon service of the order of DPHSS immediately suspending registration, the registrant shall, as instructed by DPHSS, deliver all affected controlled substances in his possession to DPHSS or his authorized agents or place all such substances under seal as prescribed by the Act.

(c) All suspensions shall continue in effect until the conclusion of all proceedings in the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by DPHSS or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause, which request may be granted by DPHSS, who shall fix the date for such hearing as early as reasonably possible.

§41621. Extension of Registration Pending Final Order.

In the event that an applicant for renewal (who is doing business under a registration previously granted and not revoked or suspended) has applied for renewal at least 30 calendar days before the date on which the existing registration is due to expire, and DPHSS has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be renewed and continued in effect until the date on which DPHSS, if and when, issues the order.

§41622. Order to Show Cause.

(a) If, upon examination of the application for registration from an applicant and other information regarding that applicant, DPHSS is unable to make the determination by the applicable provisions of the Act to register the applicant, or decides to deny the application,

DPHSS shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information regarding any registrant, DPHSS determines that the registration of such registrant is subject to suspension or revocation pursuant to the Act, DPHSS shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the registrant to appear before the DPHSS at a time and place stated in the order, which shall not be less than thirty (30) calendar days after the date of receipt of the order. This order to show cause shall also contain the statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for hearing pursuant to the Administrative Adjudication Law. If hearing is requested, DPHSS shall hold a hearing at the time and place stated in the order, pursuant to these rules regarding hearings.

(e) When authorized by these rules and the Act, any agent of DPHSS may serve the order to show cause.

(f) If the registrant or applicant does not request a hearing within the time limit as stated in the Administrative Adjudication Law, then DPHSS may proceed as provided by law.

§41623. Hearings Generally.

(a) In a case where DPHSS shall hold a hearing on any registration or application, the procedures for such hearings shall be governed by the Administrative Adjudication Law.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or under any other law of Guam.

§41624. Response to Order to Show Cause.

(a) After the filing of and service upon the registrant of an order to show cause, the registrant has fifteen (15) calendar days after service of the order in which to reply. The registrant may:

(1) Request a hearing.

(2) Object to the order upon the ground that it does not state the act or omissions upon which DPHSS may proceed to take action as stated in the order.

(3) Object to the form of the accusation on the grounds that it is so indefinite or uncertain that he cannot identify the allegations for preparative defense.

(4) Admit to the accusation in whole or in part.

(5) Prepare and submit new matter by way of his defense.

§41625. Request for Hearing.

A simple request for a hearing shall be deemed a specific denial of all parts of the accusation contained within the order to show cause, which are not expressly admitted. Said notice of defense shall be in writing signed by or on behalf of the applicant or registrant and shall state his mailing address and physical address, if different.

§41626. Filing of Response.

The registrant or applicant shall file his response to the order not more than fifteen (15) calendar days after the service of the order upon him.

§41627. Failure to File a Notice.

A failure to file a notice of defense or any notice indicating that the applicant or registrant desires a hearing and will appear upon the date stated in the order to show cause shall constitute a waiver of the applicant or registrant's right to a hearing, but DPHSS at its discretion may grant a hearing.

§41628. Notice.

DPHSS shall include with the order to show cause served upon the applicant or registrant a notice of defense entitled as such which may be in any form satisfactory to DPHSS. Also, DPHSS shall include a notice stating that the applicant or registrant waives a hearing unless a reply is received requesting the same or stating defense or defenses to the order within the time limit as stated below of these rules. This notice shall be in substantially the form: *'Unless notice, signed by or on behalf of the applicant or registrant, is delivered or mailed to the Director within fifteen (15) calendar days after receipt of the order to show cause or, at least, not less than ten (10) calendar days prior to the hearing date as stated in the order to show cause, the Director of the Department of Public Health and Social Services may proceed upon the order without a hearing. The notice of the hearing may be delivered or mailed by using the enclosed form, or any other notice of similar intent, to the Director of the Department of Public Health and Social Services, Government of Guam, Hagatna, Guam, or by personal delivery to the office of the Director, Department of Public Health and Social Services, Mangilao.'*

§41629. Serving of Order to Show Cause.

Service of the order to show cause may be made by any person so delegated by DPHSS by personally serving the applicant or registrant or by sending the order to show cause by registered mail to the last known address of the applicant or registrant as contained within his

application or registration files, or by leaving a copy of the order and accompanying papers at his usual place of residence or business with some person of suitable age and discretion residing or working therein.

§41630. Serving of Other Materials.

All other papers required to be served upon the applicant or registrant may be served in the manner of the order.

§41631. Amended or Supplemental Orders.

At any time before the matter is submitted for a decision, DPHSS may file or permit the filing of amended or supplemental orders. All parties shall be notified if this occurs. If the amended or supplemental orders present new charges, DPHSS shall afford the applicant or registrant a reasonable opportunity to prepare his defense thereto. Unless DPHSS orders in the individual case, the applicant or registrant shall not be entitled to further pleading. New charges shall be deemed controverted and any objections to the amended or supplemental order may be made orally and shall be noted on the record.

§41632. Time and Place of Hearing.

The time and place of the hearing shall be as stated on the order to show cause.

§41633. Order to Show Cause Form.

The order to show cause shall be in substantially the following form, but may include any other information and the charges:

GOVERNMENT OF GUAM

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES

IN RE THE APPLICATION OF)

)

(Applicant) under the Uniform *)* *ORDER TO SHOW CAUSE*

Controlled Substances Act *)*

)

You, (name of applicant or registrant) are hereby commanded to appear before the Director of the Department of Public Health and Social Services or his delegate on_____ day of_____, _____and show cause as to why your (application or registration) under the Uniform Controlled Substances Act should not be (denied, suspended, or revoked) for the following reasons:

1. (here follows a list of the specifications and reasons for such denial, suspension or revocation).

You may submit to the Director at the following address:

Director of the Department of Public Health and Social
Services Government of Guam
123 Chalan Kareta
Mangilao, Guam 96913-6304

or

Office of the Director
Department of the Public Health and Social Services
Mangilao, Guam
or their succeeding addresses

a notice that you intend to appear before the Director or his delegate at the hearing scheduled on the above date. You may also submit to the Director any objections or defenses which you might have within 15 days of the time this notice was served upon you or at least, then (10) days prior to the date of the hearing. If you fail to submit any notice or objections or defenses, then it will be assumed that you have waived your right to a hearing and the Director or his delegate may proceed to a decision in your case at or after the date and time for the hearing set forth above. Date this (month) and (year).

Director of the Department Public Health and Social Services

By (delegate)

§41634. Subpoena.

Before the hearing has commenced, DPHSS shall issue subpoena and subpoena *duces tecum* at the request of any party in accordance with the provisions of Section 1985 of the Code of Civil Procedure. After the hearing has commenced, the Director or hearing officer sitting alone may issue such subpoena and subpoena *duces tecum* as he deems necessary.

§41635. Depositions.

Upon the verified petition of any party, DPHSS may order that the testimony of any material witness residing within or outside the island of Guam be taken by deposition in the manner prescribed by law for depositions in civil actions. The petition shall set forth the nature of the pending proceedings, the name and address of the witness whose testimony is desired, a showing of the necessity of his testimony, a showing that the witness would be unable or cannot be compelled to be present; and shall request an order requiring the witness to appear and testify before an officer named in the petition for that purpose. Where the witness resides outside

of Guam and where the agency has ordered the taking of his testimony by deposition, the agency shall obtain an order of court to that effect by filing a petition therefor in the District Court of Guam.

§41636. Power to Administer Oaths and Affirmations by DPHSS.

In any proceedings under the order to show cause or any other hearing provided for by the Act, the Director of the Department of Public Health and Social Services, or any of his duly authorized representatives, have the power to administer oaths and affirmations and to certify to official acts.

§41637. Hearing Officer.

A hearing officer shall preside over every hearing in a contested case. Said person shall be an attorney and may be an attorney in the full-time service of the government. DPHSS may request the Attorney General of Guam to assign a member of his staff as hearing officer for the case, provided that the attorney has had no prior connection with the matters involved in the hearing. The case may be heard by the agency with a hearing officer or by a hearing officer alone, in the discretion of DPHSS. The hearing officer shall preside in any event, rule upon the admission and exclusion of evidence and advise the agency on matters of law. Where the agency is holding the hearing, it shall exercise all of the powers relating to the conduct of a hearing but may delegate any or all of them to the hearing officer. Where the hearing officer alone hears the case, he shall exercise all powers relating to the conduct of the hearing.

§41638. Disqualification.

A hearing officer or member of DPHSS shall voluntarily disqualify himself and withdraw from any case in which he cannot accord a fair and impartial hearing or consideration. Any

party may request the disqualification of any hearing officer or member of the department by filing an affidavit prior to the taking of evidence at a hearing, stating with particularity the grounds upon which it is claimed that a fair and impartial hearing may not be accorded. Where the request concerns an agency member, the Director of DPHSS shall determine the issue. Should the disqualification prevent the existence of a quorum qualified to act in a particular case, the DPHSS member shall not withdraw voluntarily nor be subject to disqualification.

§41639. Granting of Continuance.

DPHSS may grant continuances at any stage of the proceeding, the need of which shall be determined by the hearing officer.

§41640. Evidences and Witnesses.

Oral evidence shall be taken only upon oath or affirmation. Each party shall have the right to call and examine witnesses, to introduce exhibits, to cross-examine opposing witnesses on any matter relevant to the issues even though the matter was not covered in the direct examination, to impeach any witness regardless of which party first called him to testify and to rebut the evidence against him. If the respondent does not testify in his own behalf, he may be called and examined as if under cross-examination.

§41641. Admission of Relevant Evidence.

This hearing need not be conducted according to the rules relating to evidence and witnesses. Any relevant evidence shall be admitted if it is evidence which responsible persons are accustomed to rely upon in the conduct of serious affairs, regardless of the existence of any common law or statutory rules which might make improper the admission of such evidence over objection in civil actions. Hearsay evidence may be used to supplement or explain

direct evidence but shall not be sufficient by and of itself to support a finding, unless it would be effective to the same extent as recognized in civil actions. Irrelevant and unduly repetitive evidence may be excluded.

§41642. Matter not covered in Administrative Adjudication Law and Uniform Controlled Substances Act.

Any matter not covered by these rules and regulations, the Administrative Adjudication Law or by the Uniform Controlled Substances Act, shall be decided by the agency or hearing officer before whom the matter was presented.

§41643. Security Requirements Generally.

(a) All applicants and registrants shall provide effective controls and procedures to deter and guard against theft and diversion of controlled substances. Whether a registrant has provided effective controls against diversion shall be determined by DPHSS using the requirements set forth in these rules and the Act.

(b) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in these rules when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business

operations.

§41644. Physical Security for all Registrants.

Persons registered under this Act shall maintain security in conformance with the security requirements of Federal law and accordance to other requirements stated in these rules.

§41645. Security for Pharmacies.

All pharmacies dispensing controlled substances in Schedules II through *N* shall be equipped with an alarm within its premises which shall transmit a signal directly to a central station protection company or the Guam Police Department, or a 24-hour control station operated by the registrant. An exemption to this section may be granted by the DPHSS to a pharmacy if the establishment can provide reasonable justification, in writing, for not installing such system.

§41646. Increase in Security Requirements.

(a) In evaluating the overall security system of a registrant, DPHSS may consider, but is not limited to, any of the following factors as DPHSS may deem relevant to the need for stricter compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, schedule, usable powders or non-usable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on

security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems;

(9) The adequacy of electric detection and alarm systems and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel; and

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

§41647. Inspection: How often, Authority, and Consent.

(a) DPHSS may make administrative inspections of registered establishments or activity

based upon administrative probable cause. Such warrant shall be issued upon the affidavit of duly authorized persons and sworn to before a judge of the Superior Court of Guam, pursuant to the Act.

(b) An inspection, through the use of administrative warrant, shall be carried out by a DPHSS employee duly authorized by the Director of DPHSS. Any such inspector, upon stating his purpose and presenting to the owner, operator or agent in charge of the premises to be inspected his appropriate credentials, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

(c) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected. Informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected. The written consent shall contain the following information:

(1) That he (the owner, operator, or agent in charge of the premise) has been informed of his constitutional right not to have an administrative inspection made without an administrative inspection warrant;

(2) That he has the right to refuse to consent to such an inspection;

(3) That the consent given by him is voluntary and without threats of any kind; and

(4) That he may withdraw his consent anytime during the inspection.

(d) The written consent shall be produced in duplicate with the original retained by the inspector, and the duplicate to be given to the person inspected.

§41648. Prescription Information.

All prescriptions for controlled substances shall provide the information mandated by Federal law and any other requirements stated elsewhere in these rules and the Act.

§41649. Printing and Signing of Prescription.

Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.

§41650. Identification.

Upon receipt of a prescription for controlled substance, a pharmacist must verify the identification of that person to whom the prescription is written for by examining his valid and current picture identification. Valid and current picture identification shall be an official:

(a) Government of Guam Identification Card;

(b) Passport;

(c) Guam Driver's license;

(d) Military identification card; or

(e) Any other legal picture identification the Director deems acceptable.

§41651. Submitting of Prescription by Third Party.

In the event a prescription for controlled substance is brought to a pharmacy by an individual other than the person the prescription is written for, the pharmacist shall verify the identification of that individual before the order is filled, and the pharmacist shall print on the back of that prescription:

(a) The individual's name; and

(b) The individual's identification number.

§41652. Acquisition of Signature.

Prior to the actual dispensing of a controlled substance, a pharmacist must obtain a signature of the individual submitting a prescription for controlled substances listed in Schedules II, ill, and IV. The signature shall be written on the back of the prescription.

§41653. Effective Date.

These rules shall be effective after ninety (90) calendar days have elapsed from the dated of filing with the Legislative Secretary. At that time, all other rules and regulations or parts of other rules and regulations that conflict with these rules are repealed.

§41654. Severability.

If any provision or application of any provision of these rules is held invalid, that invalidity shall not affect the other provisions or applications of these rules."

RULES GOVERNING THE MANUFACTURE, DISTRIBUTION, AND DISPENSING OF CONTROLLED SUBSTANCES

DIVISION OF ENVIRONMENTAL HEALTH
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
123 CHALAN KARETA
MANGILAO, GUAM 96910-6304

Adopted pursuant to the Administrative Adjudication Law
Public Hearing: June 26, 2015
Submitted to Legislature:
Effective Date:

ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000.00) annually. As provided in § 9301(i) of Title 5 GCA, Chapter 9, Article 3, an economic impact statement is not required for these proposed rules.

"Article 16

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§41601. Purpose.

The purpose of these rules is to regulate the lawful manufacture, distribution, and dispensing of controlled substances through registration and control to prevent the diversion of legitimately produced controlled substances into illegitimate channels.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (i.e., inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion.

These rules do not provide a comprehensive, regulated framework for providing medical cannabis to individuals, in which the Joaquin (KC) Concepcion II Compassionate Cannabis Use Act of 2013 identifies nine (9) debilitating medical conditions for which a patient may receive medical cannabis. These rules also do not regulate practitioners, patients and organizations that participate in the medical cannabis system, nor does it establish specific standards and procedures for registering medical cannabis patients, designated caregivers, physicians for humans, producers, and dispensaries to protect the health, safety, and welfare of the residents and patients of Guam, by prescribing the manner in which medical cannabis is regulated. Nothing in these rules and regulations is intended to address any matters related to requiring a physician to certify the use of medical cannabis for a patient; require the accommodation or protection for any employee for the medical use of cannabis in any place of employment; any matters involving banking and financial services of a medical cannabis facility or business; any matters involving local or federal law enforcement actions; or any matters involving the medical use of cannabis by an immigrant or foreign national. The Department or its employees shall not be liable for any deleterious outcomes

from the medical use of cannabis by any patient, or from an individual's participation as a caregiver, employee or physician, or from the operation of a cannabis dispensary, cultivation site, or laboratory.

§41602. Authority.

Section 67.301 of P.L. 24-149, an Act to Repeal and Reenact Chapter 67 of Title 9, Guam Code Annotated, authorizes the Director to promulgate rules providing for the registration and control of the manufacture, distribution, and dispensing of controlled substances within Guam.

§41603. Title.

These rules and regulations shall be known and cited as the *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances* or the *Rules for Pharmaceutical Controlled Substances*.

§41604. Definitions.

As used in these rules:

(a) *'Act'* shall mean P.L. 24-149, an Act to Repeal and Reenact Chapter 67, Title 9, Guam Code Annotated, which is also known as the Uniform Controlled Substances Act.

(b) *'Cannabis'* or *'Marijuana' or "Marihuana'* means all parts of the plant of the genus *Cannabis sp.*, whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed, or its resin, including marijuana concentrate. *Cannabis sp.* does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other products.

(c) *'CSR'* shall mean the Guam Controlled Substances Registration issued by the Department.

(d) *'DEA'* shall mean the United States Drug Enforcement Administration.

(e) *'Department'* or *'DPHSS'* shall mean the Department of Public Health and Social Services.

(f) *'Director'* shall mean the Director of the Department of Public Health and Social Services, or his designee.

(g) *'Dispense'* means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(h) *'Distribute'* means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(i) *'Individual registrant'* shall mean a physician, dentist, veterinarian, podiatrist or other lawfully licensed person permitted on Guam to dispense controlled substances in the course of his professional practice, but does not include an institutional registrant, a pharmacy, or a pharmacist.

(j) *'Institutional registrant'* shall mean a hospital, clinic, or other lawfully licensed establishment wherein dispensing of controlled substances are permitted by Guam in the course of that establishment's business, but does not include a pharmacy.

(k) *'Manufacture'* means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(l) *'Pharmacist'* means any pharmacist licensed by the Department of Public Health and Social Services' Health Professional Licensing Office to dispense controlled substances and shall include any other person (e.g. pharmacist intern) authorized by the Department of Public Health and Social Services' Health Professional Licensing Office to prescribe, dispense or store controlled substances under the supervision of a pharmacist licensed by Department of Public Health and Social Services' Health Professional Licensing Office.

(m) *'Pharmacy'* shall mean a lawfully licensed pharmacy permitted on Guam to dispense controlled substances in the course of that establishment's business.

(n) *'Practitioner'* means a physician, dentist, veterinarian, scientific investigator, pharmacist, pharmacy, hospital, government operated or government contracted animal shelter, or other person licensed, registered, or otherwise permitted, by Guam, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(o) *'Registrant'* shall mean any person or establishment registered pursuant to the Guam Uniform Controlled Substances Act.

(p) *'Regulated person'* means a person who manufactures, distributes, dispensed, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for a transaction involving a listed chemical, a tableting machine, or an encapsulating machine (including doing business as a Reverse Distributor or Reverse Processor).

(q) *'Reverse distributor'* or *'Reverse processor'* means a person who receives controlled substances acquired from another Drug Enforcement Administration and CSR registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.

Unless otherwise stated in these rules, the definitions in the Act shall also be the definitions of these rules.

§41605. Guam Controlled Substances Registration.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any listed chemical compound contained in the controlled substances listing or any controlled substance other than Cannabis and Cannabis products, or who owns and operates a tableting machine, an encapsulating machine or who acts as a broker or trader for an transaction involving a listed chemical, a tableting machine, or an encapsulating machine (including doing business as a reverse distributor or reverse processor) shall annually obtain a Guam Controlled Substances Registration unless exempted by law or as otherwise exempted by these rules. Only persons or institutions directly engaged in such activities are required to obtain a registration. (For example, a

stockholder or parent corporation of a corporation manufacturing controlled substances are not considered directly engaged in such activities, and need not be registered.)

(b) A practitioner must be registered with DPHSS before dispensing a controlled substance or conducting research with respect to a controlled substance included in Schedules II through V. DPHSS need not require separate registration under this Article for a practitioner engaging in research with non-narcotic substances included in Schedules II through V if the registrant is already registered under this Act in another capacity, or if the practitioner is already legally registered in Guam to dispense or conduct research on Cannabis. A practitioner registered under Federal law to conduct research with a substance included in Schedule I may conduct research with the substance in Guam upon furnishing DPHSS evidence of the Federal registration.

(c) A reverse distributor or reverse processor must be registered with DEA and DPHSS before receiving controlled substances acquired from another DEA and CSR registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or where necessary, processing such substances or arranging for processing such substances for disposal.

(1) The registration and other requirements for reverse distributors or reverse processors shall be the same as those currently imposed on distributors, to include but not limited to, accountability, security, inventory, recordkeeping, and reporting requirements.

(d) Upon approval by DPHSS, the registrant shall receive a Guam Controlled Substances Registration certificate that shall state:

(1) Name of the registrant;

(2) Controlled substance schedules the registrant is authorized to handle;

(3) Physical location of the principal place of business/practice, and mailing address if different from the physical address;

(4) Guam Controlled Substances Registration number, as provided by DPHSS, and its expiration date;

(5) Signature of the Director; and

(6) Other applicable information determined by the Director.

(e) Registrant shall post the Guam CSR certificate at the physical location of practice or business where an authorized inspector, as designated by DPHSS, will be able to inspect the certificate.

(f) The Director may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest.

§41606. Separate Registrations for Separate Locations, and Transfer of Locations.

(a) A separate registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed by a person or business.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed.

(1) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised, but which neither contains such substances nor serves as a distribution point for filling sales orders; and

(2) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise

dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained; and

(3) A warehouse where controlled substances are stored by or on behalf of the registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to a person not required to register by virtue of the Guam Uniform Controlled Substances Act.

(c) A registrant who intends to move his place of practice or business must request a modification of his Guam CSR certificate. The request must be made in writing and approved prior to the effective date of the move. If any registrant moves his place of business or practice without requesting and obtaining prior approval in the form of a modification of his Guam CSR certificate by DPHSS, then his registration shall automatically become invalid regardless of the expiration date.

§41607. Application.

(a) Any practitioner who is required to be registered and who is not so registered may apply for registration at any time. No practitioner required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a CSR is issued by the Director to such person.

(b) Interested persons may pick up the application for CSR at the Division of Environmental Health of DPHSS or may request the application to be mailed.

(c) The application shall state the following:

(1) Name of applicant;

(2) Name of business or practice;

(3) Physical and mailing address of business or practice;

(4) Telephone and facsimile numbers;

(5) Schedule(s) of controlled substances utilized;

(6) Licensed profession; and

(7) Any other information, or materials, deemed necessary by DPHSS, including but not limited to, any surrender, suspension, or revocation of controlled substances privileges from the DEA or DPHSS, or from any other state or federal agency, and any conviction record involving any controlled substances at any time and under any law governing the same.

(d) Renewal application for CSR will be mailed to the address indicated on the registrant's last application at least sixty (60) days prior to the date of expiration. Any registrant not receiving the renewal application 45 days prior to date of expiration should immediately notify DPHSS.

(f) Any person who is registered may apply for a renewal, provided it is not more than 60 days from the expiration date stated on his CSR.

(g) Any person applying for a renewal after 30 days or more from the expiration date stated on his CSR shall be considered a new applicant.

§41608. Filing of Application.

(a) All applications shall be delivered to the Division of Environmental Health of the Department of Public Health in Mangilao or mailed to the Division of Environmental Health, the Department of Public Health and Social Services, 123 Chalan Kareta Mangilao, Guam 96913-

6304.

(b) The post-marked date shall be considered the date of receipt by DPHSS for all applications received by mail. The date of acknowledged payment for application shall be considered the date of receipt by DPHSS for all other applications not received by mail.

(c) Only the original, complete application with appropriate payment shall be accepted and processed. Any photocopy, incomplete or illegible application, or any application not written in indelible ink, or missing a required document or payment, shall not be processed and shall be returned via mail.

§41609. Additional Information.

(a) DPHSS may require an applicant to submit such documents or written statements of fact as DPHSS deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within ten working days after being requested to do so shall be deemed a waiver by the applicant to present such documents or facts for consideration by DPHSS in granting or denying the application.

(b) All registrants applying for the Guam Controlled Substances Registration with DPHSS, or already registered with DPHSS, must provide a copy of their most recent DEA Controlled Substances Registration Certificate (federal registration) once that certificate becomes available to the registrant.

§41610. Amendments to and Withdrawals of Applications.

An application may be amended or withdrawn without permission of DPHSS at any time before the applicant receives an order to show cause pursuant to the Act. An application may be amended or withdrawn as a matter of course due to a change in the applicant's federal controlled

substances status or registration.

§41611. Fee Amounts.

(a) For each initial Controlled Substances Registration:

(1) To manufacture controlled substances, the applicant shall pay a fee of **One Thousand Dollars ($1000).**

(2) To distribute controlled substances, the applicant shall pay a fee of **Five Hundred Dollars ($500).**

(3) To dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants shall pay a fee of **Five Hundred Dollars ($500),** and a pharmacy shall pay a fee of **Five Hundred Dollars ($500).**

(b) For each renewal of Controlled Substances Registration:

(1) To manufacture controlled substances, the registrant shall pay fee of **One Thousand Dollars ($1000).**

(2) To distribute controlled substances, the registrant shall pay fee of **Five Hundred Dollars ($500).**

(3) For each renewal registration to dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants shall pay a fee of **Five Hundred Dollars ($500),** and pharmacy shall pay a fee of **Five Hundred Dollars ($500).**

(c) Any registrant who submits its renewal application thirty days after the expiration date shall be considered a new applicant and shall pay the required initial fee.

(d) Any registrant who has a current CSR and is required to correct or update such CSR due to change of address or any other reasons requiring the re-issuance of another CSR, shall pay a fee of Ten Dollars ($10.00).

(e) Registration and renewal fees shall be paid at the time when application for registration or renewal is submitted for filing. Payment shall be made in the form of a certified or cashier's check, money order, or personal or business check drawn through a locally existing bank. Initial application and renewal application fees are non-refundable.

§41612. Persons Exempt from Fee.

(a) Department of Public Health and Social Services shall exempt from payment of a fee for registration or renewal any official, employee, or entity of DPHSS who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense such substances, to conduct research and instructional activities or chemical analysis with such substances or any combination thereof in the course of his or its official duties or employment.

(b) Department of Public Health and Social Services shall exempt from payment of a fee for registration or renewal any official, employee, or entity of a law enforcement agency laboratory, including laboratories of the DEA, which is authorized to obtain and transfer controlled substances for use as standards in chemical analysis, Guam Police Forensic Laboratory, who or which is authorized under the Attorney General of Guam or the Judiciary of Guam to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this subchapter. The Attorney General of Guam may authorize an official, employee, or entity to

possess controlled substances, by obtaining such substances from investigations, examination of scenes of crime, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court, and to conduct research or chemical analysis with such substances or any combination thereof in the course of his or its official duties or employment. Such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration.

(c) In order to claim exemption from payment of a registration or renewal fee, the registrant shall submit a statement wherein the registrant's supervising officer certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or otherwise be permitted to handle controlled substances.

(d) Exemption from payment of a registration or renewal fee does not exempt the registrant from any other requirements or duties prescribed by law.

§41613. Exemption of Agents and Employees; Affiliated Practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment.

(b) Practitioner (including an intern, resident or foreign physician) who is an employee of a registered hospital or clinic may dispense controlled substances under that hospital's or clinic's registration provided that:

(1) Such dispensing is done in the usual course of his professional practice as an employee of the institution;

(2) Such employed practitioner is authorized or permitted to do so by the laws of Guam;

(3) The hospital or the institution has verified that the practitioner is so permitted to dispense, administer, or prescribe controlled substances in Guam;

(4) Such practitioner is acting only within the scope of his employment in the hospital or institution;

(5) The hospital or the institution authorizes the practitioner to dispense under the institution's registration and designates a specific internal code number for each practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the hospital's or institution's Guam CSR number, preceded by a hyphen (ex: HOO1-01 or COO1-A1); and

(6) The hospital or the institution provides a current list of internal codes with corresponding individual practitioners to DPHSS, and is made available at all times to pharmacies registered with the Department and law enforcement agencies upon request for the purpose of verifying the authority of the administering, dispensing, and prescribing practitioner.

§41614. Exemption of Certain Military and Other Personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, U.S. Navy, U.S. Marine Corp., U.S. Air Force, U.S. Coast Guard, and U.S. Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase controlled substances in the course of his official duties. Prescriptions written by persons mentioned in this section may be honored by a pharmacy outside the military installation, if so

desired by the pharmacist, provided that:

(1) Pharmacist makes a reasonable effort to determine that the prescription is legitimate, which may include a call back to the prescriber, and/or other good faith efforts to insure the identity; and

(2) The prescription has the branch of service/agency, service identification of practitioner, practitioner's and patient's name and address, date, and instructions.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities and pay the required fee.

§41615. Exemption of Law Enforcement Officials.

(a) The requirement of registration is waived for the following persons in circumstances described in this section:

(1) Any officer or employee of a Government of Guam agency who is engaged in the enforcement of any Guam law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(2) Any officer or employee of the United States DEA, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties, including personnel in the investigative services of the military forces stationed on Guam.

(3) Any officer or employee of Guam, or any political subdivision or agency

thereof, who is engaged in the enforcement of any Guam law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.

(4) Any official exempted by this section may, when acting in the course of his official duties, possess a controlled substance and distribute such substance to any other official exempted by this section and acting in the course of his official duties.

(5) Any official exempted by this section may procure a controlled substance in the course of an inspection, in accordance with the Act, or in the course of any criminal investigation involving the person from whom the substance was procured.

(6) In order to enable law enforcement agency laboratories, including laboratories of the DEA, to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in section 515(d) of the federal Controlled Substances Act (21 U.S.C. 885(d)). For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

(7) In addition to the activities authorized under a registration to conduct chemical analysis pursuant to Title 21 of the Code of Federal Regulations, Part 1301, §1301.13(e)(1)(ix), laboratories of the DEA shall be authorized to manufacture or import controlled substances for any lawful purpose, to distribute or export such substances to any

person, and to import and export such substances in emergencies without regard to the requirements of Title 21 of the Code of Federal Regulations, Part 1312 if a report concerning the importation or exportation is made to the Drug Operations Section of the DEA within 30 days of such importation or exportation.

§41616. Exemption of Civil Defense Officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is in accordance with applicable local and federal laws governing controlled substances and any emergency preparedness plans of Civil Defense.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization within his jurisdiction proclaimed by the Governor or by a concurrent resolution of the Guam Legislature or by the Civil Defense network on Guam, which official, in the course of his official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on the official form provided by Civil Defense.

(c) Such forms may be used and are valid only during a state of emergency or disaster in which the organization using such forms has civil defense or disaster relief

jurisdiction, and which shall state the position of the user and the nature and legal designation of the emergency or disaster. Any person registered under the Act may complete such forms. The organization using civil defense emergency order forms will be deemed to be registered under the Act for purposes of record keeping.

§41617. Administrative Review Generally.

DPHSS may inspect or cause to be inspected the establishment of an applicant or registrant, pursuant to the Act. DPHSS shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of the Act have been met by the applicant.

§41618. Certificate of Registration.

DPHSS shall issue a certificate of registration to an applicant if the issuance of registration or renewal is required under the applicable provisions of the Act. In the event that the issuance of registration or renewal is not appropriate, DPHSS shall deny or refuse the application. Before denying or refusing any application, DPHSS shall issue an order to show cause pursuant to these rules. If requested by the applicant, DPHSS shall hold a hearing on the application pursuant to these rules and the Administrative Adjudication Law.

§41619. Suspension or Revocation of Registration.

(a) DPHSS may suspend any registration pursuant to the Act for any reasonable and justifiable period of time as determined by DPHSS.

(b) DPHSS may revoke any registration pursuant to the Act.

(c) Before revoking or suspending any registration, DPHSS shall issue an order to show cause pursuant to the Act and, if requested by the registrant, shall hold a hearing pursuant to

the Act and the Administrative Adjudication Law. Notwithstanding the requirements of this section, however, DPHSS may suspend any registration pending a final order pursuant to these rules.

(d) Upon service of the order of DPHSS suspending or revoking registration, the registrant shall immediately surrender his certificate of registration to DPHSS. In addition, the registrant, as instructed by DPHSS, shall deliver all controlled substances in his possession to DPHSS for destruction.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by such revocation or suspension. No fees shall be required to be paid for the new certificate. The registrant shall surrender the old certificate of registration to DPHSS. In addition, the registrant shall, as instructed by DPHSS, deliver to DPHSS, or to authorized agents, all of the particular controlled substance or substances affected by the revocation or suspension that are in his possession for destruction.

§41620. Suspension of Registration Pending Final Order.

(a) DPHSS may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where DPHSS finds that there is an imminent danger to the public health or safety. If DPHSS so suspends, DPHSS shall serve with the order to show cause pursuant to the Act an order of immediate suspension which shall contain the statement of DPHSS' findings regarding the danger to the public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly

surrender his certificate of registration to DPHSS. Also, upon service of the order of DPHSS immediately suspending registration, the registrant shall, as instructed by DPHSS, deliver all affected controlled substances in his possession to DPHSS or his authorized agents or place all such substances under seal as prescribed by the Act.

(c) All suspensions shall continue in effect until the conclusion of all proceedings in the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by DPHSS or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause, which request may be granted by DPHSS, who shall fix the date for such hearing as early as reasonably possible.

§41621. Extension of Registration Pending Final Order.

In the event that an applicant for renewal (who is doing business under a registration previously granted and not revoked or suspended) has applied for renewal at least 30 calendar days before the date on which the existing registration is due to expire, and DPHSS has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be renewed and continued in effect until the date on which DPHSS, if and when, issues the order.

§41622. Order to Show Cause.

(a) If, upon examination of the application for registration from an applicant and other information regarding that applicant, DPHSS is unable to make the determination by the applicable provisions of the Act to register the applicant, or decides to deny the application,

DPHSS shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information regarding any registrant, DPHSS determines that the registration of such registrant is subject to suspension or revocation pursuant to the Act, DPHSS shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the registrant to appear before the DPHSS at a time and place stated in the order, which shall not be less than thirty (30) calendar days after the date of receipt of the order. This order to show cause shall also contain the statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for hearing pursuant to the Administrative Adjudication Law. If hearing is requested, DPHSS shall hold a hearing at the time and place stated in the order, pursuant to these rules regarding hearings.

(e) When authorized by these rules and the Act, any agent of DPHSS may serve the order to show cause.

(f) If the registrant or applicant does not request a hearing within the time limit as stated in the Administrative Adjudication Law, then DPHSS may proceed as provided by law.

§41623. Hearings Generally.

(a) In a case where DPHSS shall hold a hearing on any registration or application, the procedures for such hearings shall be governed by the Administrative Adjudication Law.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or under any other law of Guam.

§41624. Response to Order to Show Cause.

(a) After the filing of and service upon the registrant of an order to show cause, the registrant has fifteen (15) calendar days after service of the order in which to reply. The registrant may:

(1) Request a hearing.

(2) Object to the order upon the ground that it does not state the act or omissions upon which DPHSS may proceed to take action as stated in the order.

(3) Object to the form of the accusation on the grounds that it is so indefinite or uncertain that he cannot identify the allegations for preparative defense.

(4) Admit to the accusation in whole or in part.

(5) Prepare and submit new matter by way of his defense.

§41625. Request for Hearing.

A simple request for a hearing shall be deemed a specific denial of all parts of the accusation contained within the order to show cause, which are not expressly admitted. Said notice of defense shall be in writing signed by or on behalf of the applicant or registrant and shall state his mailing address and physical address, if different.

§41626. Filing of Response.

The registrant or applicant shall file his response to the order not more than fifteen (15) calendar days after the service of the order upon him.

§41627. Failure to File a Notice.

A failure to file a notice of defense or any notice indicating that the applicant or registrant desires a hearing and will appear upon the date stated in the order to show cause shall constitute a waiver of the applicant or registrant's right to a hearing, but DPHSS at its discretion may grant a hearing.

§41628. Notice.

DPHSS shall include with the order to show cause served upon the applicant or registrant a notice of defense entitled as such which may be in any form satisfactory to DPHSS. Also, DPHSS shall include a notice stating that the applicant or registrant waives a hearing unless a reply is received requesting the same or stating defense or defenses to the order within the time limit as stated below of these rules. This notice shall be in substantially the form: *'Unless notice, signed by or on behalf of the applicant or registrant, is delivered or mailed to the Director within fifteen (15) calendar days after receipt of the order to show cause or, at least, not less than ten (10) calendar days prior to the hearing date as stated in the order to show cause, the Director of the Department of Public Health and Social Services may proceed upon the order without a hearing. The notice of the hearing may be delivered or mailed by using the enclosed form, or any other notice of similar intent, to the Director of the Department of Public Health and Social Services, Government of Guam, Hagatna, Guam, or by personal delivery to the office of the Director, Department of Public Health and Social Services, Mangilao.'*

§41629. Serving of Order to Show Cause.

Service of the order to show cause may be made by any person so delegated by DPHSS by personally serving the applicant or registrant or by sending the order to show cause by registered mail to the last known address of the applicant or registrant as contained within his

application or registration files, or by leaving a copy of the order and accompanying papers at his usual place of residence or business with some person of suitable age and discretion residing or working therein.

§41630. Serving of Other Materials.

All other papers required to be served upon the applicant or registrant may be served in the manner of the order.

§41631. Amended or Supplemental Orders.

At any time before the matter is submitted for a decision, DPHSS may file or permit the filing of amended or supplemental orders. All parties shall be notified if this occurs. If the amended or supplemental orders present new charges, DPHSS shall afford the applicant or registrant a reasonable opportunity to prepare his defense thereto. Unless DPHSS orders in the individual case, the applicant or registrant shall not be entitled to further pleading. New charges shall be deemed controverted and any objections to the amended or supplemental order may be made orally and shall be noted on the record.

§41632. Time and Place of Hearing.

The time and place of the hearing shall be as stated on the order to show cause.

§41633. Order to Show Cause Form.

The order to show cause shall be in substantially the following form, but may include any other information and the charges:

GOVERNMENT OF GUAM

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES

IN RE THE APPLICATION OF)

)	
(Applicant) under the Uniform)	*ORDER TO SHOW CAUSE*
Controlled Substances Act)	
)	

*You, (name of applicant or registrant) are hereby commanded to appear before the Director of the Department of Public Health and Social Services or his delegate on*_____ *day of*_____, _____*and show cause as to why your (application or registration) under the Uniform Controlled Substances Act should not be (denied, suspended, or revoked) for the following reasons:*

1. (here follows a list of the specifications and reasons for such denial, suspension or revocation).

You may submit to the Director at the following address:

Director of the Department of Public Health and Social Services Government of Guam
123 Chalan Kareta
Mangilao, Guam 96913-6304

or

Office of the Director
Department of the Public Health and Social Services
Mangilao, Guam
or their succeeding addresses

a notice that you intend to appear before the Director or his delegate at the hearing scheduled on the above date. You may also submit to the Director any objections or defenses which you might have within 15 days of the time this notice was served upon you or at least, then (10) days prior to the date of the hearing. If you fail to submit any notice or objections or defenses, then it will be assumed that you have waived your right to a hearing and the Director or his delegate may proceed to a decision in your case at or after the date and time for the hearing set forth above. Date this (month) and (year).

Director of the Department Public Health and Social Services

By (delegate)

§41634. Subpoena.

Before the hearing has commenced, DPHSS shall issue subpoena and subpoena *duces tecum* at the request of any party in accordance with the provisions of Section 1985 of the Code of Civil Procedure. After the hearing has commenced, the Director or hearing officer sitting alone may issue such subpoena and subpoena *duces tecum* as he deems necessary.

§41635. Depositions.

Upon the verified petition of any party, DPHSS may order that the testimony of any material witness residing within or outside the island of Guam be taken by deposition in the manner prescribed by law for depositions in civil actions. The petition shall set forth the nature of the pending proceedings, the name and address of the witness whose testimony is desired, a showing of the necessity of his testimony, a showing that the witness would be unable or cannot be compelled to be present; and shall request an order requiring the witness to appear and testify before an officer named in the petition for that purpose. Where the witness resides outside

of Guam and where the agency has ordered the taking of his testimony by deposition, the agency shall obtain an order of court to that effect by filing a petition therefor in the District Court of Guam.

§41636. Power to Administer Oaths and Affirmations by DPHSS.

In any proceedings under the order to show cause or any other hearing provided for by the Act, the Director of the Department of Public Health and Social Services, or any of his duly authorized representatives, have the power to administer oaths and affirmations and to certify to official acts.

§41637. Hearing Officer.

A hearing officer shall preside over every hearing in a contested case. Said person shall be an attorney and may be an attorney in the full-time service of the government. DPHSS may request the Attorney General of Guam to assign a member of his staff as hearing officer for the case, provided that the attorney has had no prior connection with the matters involved in the hearing. The case may be heard by the agency with a hearing officer or by a hearing officer alone, in the discretion of DPHSS. The hearing officer shall preside in any event, rule upon the admission and exclusion of evidence and advise the agency on matters of law. Where the agency is holding the hearing, it shall exercise all of the powers relating to the conduct of a hearing but may delegate any or all of them to the hearing officer. Where the hearing officer alone hears the case, he shall exercise all powers relating to the conduct of the hearing.

§41638. Disqualification.

A hearing officer or member of DPHSS shall voluntarily disqualify himself and withdraw from any case in which he cannot accord a fair and impartial hearing or consideration. Any

party may request the disqualification of any hearing officer or member of the department by filing an affidavit prior to the taking of evidence at a hearing, stating with particularity the grounds upon which it is claimed that a fair and impartial hearing may not be accorded. Where the request concerns an agency member, the Director of DPHSS shall determine the issue. Should the disqualification prevent the existence of a quorum qualified to act in a particular case, the DPHSS member shall not withdraw voluntarily nor be subject to disqualification.

§41639. Granting of Continuance.

DPHSS may grant continuances at any stage of the proceeding, the need of which shall be determined by the hearing officer.

§41640. Evidences and Witnesses.

Oral evidence shall be taken only upon oath or affirmation. Each party shall have the right to call and examine witnesses, to introduce exhibits, to cross-examine opposing witnesses on any matter relevant to the issues even though the matter was not covered in the direct examination, to impeach any witness regardless of which party first called him to testify and to rebut the evidence against him. If the respondent does not testify in his own behalf, he may be called and examined as if under cross-examination.

§41641. Admission of Relevant Evidence.

This hearing need not be conducted according to the rules relating to evidence and witnesses. Any relevant evidence shall be admitted if it is evidence which responsible persons are accustomed to rely upon in the conduct of serious affairs, regardless of the existence of any common law or statutory rules which might make improper the admission of such evidence over objection in civil actions. Hearsay evidence may be used to supplement or explain

direct evidence but shall not be sufficient by and of itself to support a finding, unless it would be effective to the same extent as recognized in civil actions. Irrelevant and unduly repetitive evidence may be excluded.

§41642. Matter not covered in Administrative Adjudication Law and Uniform Controlled Substances Act.

Any matter not covered by these rules and regulations, the Administrative Adjudication Law or by the Uniform Controlled Substances Act, shall be decided by the agency or hearing officer before whom the matter was presented.

§41643. Security Requirements Generally.

(a) All applicants and registrants shall provide effective controls and procedures to deter and guard against theft and diversion of controlled substances. Whether a registrant has provided effective controls against diversion shall be determined by DPHSS using the requirements set forth in these rules and the Act.

(b) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in these rules when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business

operations.

§41644. Physical Security for all Registrants.

Persons registered under this Act shall maintain security in conformance with the security requirements of Federal law and accordance to other requirements stated in these rules.

§41645. Security for Pharmacies.

All pharmacies dispensing controlled substances in Schedules II through *N* shall be equipped with an alarm within its premises which shall transmit a signal directly to a central station protection company or the Guam Police Department, or a 24-hour control station operated by the registrant. An exemption to this section may be granted by the DPHSS to a pharmacy if the establishment can provide reasonable justification, in writing, for not installing such system.

§41646. Increase in Security Requirements.

(a) In evaluating the overall security system of a registrant, DPHSS may consider, but is not limited to, any of the following factors as DPHSS may deem relevant to the need for stricter compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, schedule, usable powders or non-usable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on

security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems;

(9) The adequacy of electric detection and alarm systems and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel; and

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

§41647. Inspection: How often, Authority, and Consent.

(a) DPHSS may make administrative inspections of registered establishments or activity

based upon administrative probable cause. Such warrant shall be issued upon the affidavit of duly authorized persons and sworn to before a judge of the Superior Court of Guam, pursuant to the Act.

(b) An inspection, through the use of administrative warrant, shall be carried out by a DPHSS employee duly authorized by the Director of DPHSS. Any such inspector, upon stating his purpose and presenting to the owner, operator or agent in charge of the premises to be inspected his appropriate credentials, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

(c) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected. Informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected. The written consent shall contain the following information:

(1) That he (the owner, operator, or agent in charge of the premise) has been informed of his constitutional right not to have an administrative inspection made without an administrative inspection warrant;

(2) That he has the right to refuse to consent to such an inspection;

(3) That the consent given by him is voluntary and without threats of any kind; and

(4) That he may withdraw his consent anytime during the inspection.

(d) The written consent shall be produced in duplicate with the original retained by the inspector, and the duplicate to be given to the person inspected.

§41648. Prescription Information.

All prescriptions for controlled substances shall provide the information mandated by Federal law and any other requirements stated elsewhere in these rules and the Act.

§41649. Printing and Signing of Prescription.

Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.

§41650. Identification.

Upon receipt of a prescription for controlled substance, a pharmacist must verify the identification of that person to whom the prescription is written for by examining his valid and current picture identification. Valid and current picture identification shall be an official:

(a) Government of Guam Identification Card;

(b) Passport;

(c) Guam Driver's license;

(d) Military identification card; or

(e) Any other legal picture identification the Director deems acceptable.

§41651. Submitting of Prescription by Third Party.

In the event a prescription for controlled substance is brought to a pharmacy by an individual other than the person the prescription is written for, the pharmacist shall verify the identification of that individual before the order is filled, and the pharmacist shall print on the back of that prescription:

(a) The individual's name; and

(b) The individual's identification number.

§41652. Acquisition of Signature.

Prior to the actual dispensing of a controlled substance, a pharmacist must obtain a signature of the individual submitting a prescription for controlled substances listed in Schedules II, ill, and IV. The signature shall be written on the back of the prescription.

§41653. Effective Date.

These rules shall be effective after ninety (90) calendar days have elapsed from the dated of filing with the Legislative Secretary. At that time, all other rules and regulations or parts of other rules and regulations that conflict with these rules are repealed.

§41654. Severability.

If any provision or application of any provision of these rules is held invalid, that invalidity shall not affect the other provisions or applications of these rules."

DRAFT PROPOSED RULES AND REGULATIONS GOVERNING THE MANUFACTURE, DISTRIBUTION, AND DISPENSING OF CONTROLLED SUBSTANCES ,DATED SEPTEMBER 5, 2017

AS SUBMITTED TO THE OFFICE OF THE GOVERNOR

Office of the Attorney General of Guam

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September 13, 2017

To	Initial	Date
TOM		9/26
RC4		
File		

James Gillan, Director
Department of Public Health and Social Services
123 Chalan Kareta
Mangilao, Guam 96913-6304

Subject: **Attorney General Approval of September 2017 Revised Proposed Rules and Regulations Governing Controlled Substances (Ref: DPHSS 15-0477)**

Dear Director Gillan:

This Office received a draft of proposed Rules and Regulations Governing Controlled Substances for Attorney General approval. However, after lengthy review, discussion, and examination of the proposed rules, a revised version of these rules was submitted for review and final approval in September of 2017. The Office of the Attorney General has completed this review of these revised proposed rules and regulations.

Pursuant to the Administrative Adjudication Law (AAL), 5 GCA § 9303, I hereby approve the attached version of the proposed Rules, which was revised in September of 2017, as to form and as to compliance with the applicable requirements of the AAL.

The current rule-making procedures provide that no rule shall become effective until after ninety (90) calendar days have elapsed from the date of filing with the Legislative Secretary. However, within this 90-day time period, the Legislature may approve, disapprove, or amend these proposed rules.

Sincerely,

E. Barrett-Anderson

ELIZABETH BARRETT-ANDERSON

RECEIVED
Director's Office
Division Of General Administration
SEP 22 2017
DPH&SS
Time: 4:00pm **Locator#:** 347

Attachment

RECEIVED
SEP 26 2017
DIVISION OF ENVIRONMENTAL HEALTH

26 GAR - PUBLIC HEALTH & SOCIAL SERVICES

DIV. 1 - DIRECTOR OF PUBLIC HEALTH & SOCIAL SERVICES

RULES GOVERNING THE MANUFACTURE, DISTRIBUTION, AND DISPENSING OF CONTROLLED SUBSTANCES

DIVISION OF ENVIRONMENTAL HEALTH
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
123 CHALAN KARETA
MANGILAO, GUAM 96910-6304

Adopted pursuant to the Administrative Adjudication Law
Public Hearing: June 26, 2015
Submitted to Legislature:
Effective Date:

ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000.00) annually. As provided in § 9301(i) of Title 5 GCA, Chapter 9, Article 3, an economic impact statement is not required for these proposed rules.

"Article 16

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§41601. Purpose.

The purpose of these rules is to regulate the lawful manufacture, distribution, and dispensing of controlled substances through registration and control to prevent the diversion of legitimately produced controlled substances into illegitimate channels.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (i.e., inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion.

These rules do not provide a comprehensive, regulated framework for providing medical cannabis to individuals, in which the Joaquin (KC) Concepcion II Compassionate Cannabis Use Act of 2013 identifies nine (9) debilitating medical conditions for which a patient may receive medical cannabis. These rules also do not regulate practitioners, patients and organizations that participate in the medical cannabis system, nor does it establish specific standards and procedures for registering medical cannabis patients, designated caregivers, physicians for humans, producers, and dispensaries to protect the health, safety, and welfare of the residents and patients of Guam, by prescribing the manner in which medical cannabis is regulated. Nothing in these rules and regulations is intended to address any matters related to requiring a physician to certify the use of medical cannabis for a patient; require the accommodation or protection for any employee for the medical use of cannabis in any place of employment; any matters involving banking and financial services of a medical cannabis facility or business; any matters involving local or federal law enforcement actions; or any matters involving the medical use of cannabis by an immigrant or foreign national. The Department or its employees shall not be liable for any deleterious outcomes

from the medical use of cannabis by any patient, or from an individual's participation as a caregiver, employee or physician, or from the operation of a cannabis dispensary, cultivation site, or laboratory.

§41602. Authority.

Section 67.301 of P.L. 24-149, an Act to Repeal and Reenact Chapter 67 of Title 9, Guam Code Annotated, authorizes the Director to promulgate rules providing for the registration and control of the manufacture, distribution, and dispensing of controlled substances within Guam.

§41603. Title.

These rules and regulations shall be known and cited as the *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances* or the *Rules for Pharmaceutical Controlled Substances.*

§41604. Definitions.

As used in these rules:

(a) *'Act'* shall mean P.L. 24-149, an Act to Repeal and Reenact Chapter 67, Title 9, Guam Code Annotated, which is also known as the Uniform Controlled Substances Act.

(b) *'Cannabis'* or *'Marijuana' or "Marihuana'* means all parts of the plant of the genus *Cannabis sp.*, whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed, or its resin, including marijuana concentrate. *Cannabis sp.* does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other products.

(c) *'CSR'* shall mean the Guam Controlled Substances Registration issued by the Department.

(d) *'DEA'* shall mean the United States Drug Enforcement Administration.

(e) *'Department'* or *'DPHSS'* shall mean the Department of Public Health and Social Services.

(f) *'Director'* shall mean the Director of the Department of Public Health and Social Services, or his designee.

(g) *'Dispense'* means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(h) *'Distribute'* means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(i) *'Individual registrant'* shall mean a physician, dentist, veterinarian, podiatrist or other lawfully licensed person permitted on Guam to dispense controlled substances in the course of his professional practice, but does not include an institutional registrant, a pharmacy, or a pharmacist.

(j) *'Institutional registrant'* shall mean a hospital, clinic, or other lawfully licensed establishment wherein dispensing of controlled substances are permitted by Guam in the course of that establishment's business, but does not include a pharmacy.

(k) *'Manufacture'* means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(l) *'Pharmacist'* means any pharmacist licensed by the Department of Public Health and Social Services' Health Professional Licensing Office to dispense controlled substances and shall include any other person (e.g. pharmacist intern) authorized by the Department of Public Health and Social Services' Health Professional Licensing Office to prescribe, dispense or store controlled substances under the supervision of a pharmacist licensed by Department of Public Health and Social Services' Health Professional Licensing Office.

(m) *'Pharmacy'* shall mean a lawfully licensed pharmacy permitted on Guam to dispense controlled substances in the course of that establishment's business.

(n) *'Practitioner'* means a physician, dentist, veterinarian, scientific investigator, pharmacist, pharmacy, hospital, government operated or government contracted animal shelter, or other person licensed, registered, or otherwise permitted, by Guam, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(o) *'Registrant'* shall mean any person or establishment registered pursuant to the Guam Uniform Controlled Substances Act.

(p) *'Regulated person'* means a person who manufactures, distributes, dispensed, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for a transaction involving a listed chemical, a tableting machine, or an encapsulating machine (including doing business as a Reverse Distributor or Reverse Processor).

(q) *'Reverse distributor'* or *'Reverse processor'* means a person who receives controlled substances acquired from another Drug Enforcement Administration and CSR registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.

Unless otherwise stated in these rules, the definitions in the Act shall also be the definitions of these rules.

§41605. Guam Controlled Substances Registration.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any listed chemical compound contained in the controlled substances listing or any controlled substance other than Cannabis and Cannabis products, or who owns and operates a tableting machine, an encapsulating machine or who acts as a broker or trader for an transaction involving a listed chemical, a tableting machine, or an encapsulating machine (including doing business as a reverse distributor or reverse processor) shall annually obtain a Guam Controlled Substances Registration unless exempted by law or as otherwise exempted by these rules. Only persons or institutions directly engaged in such activities are required to obtain a registration. (For example, a

stockholder or parent corporation of a corporation manufacturing controlled substances are not considered directly engaged in such activities, and need not be registered.)

(b) A practitioner must be registered with DPHSS before dispensing a controlled substance or conducting research with respect to a controlled substance included in Schedules II through V. DPHSS need not require separate registration under this Article for a practitioner engaging in research with non-narcotic substances included in Schedules II through V if the registrant is already registered under this Act in another capacity, or if the practitioner is already legally registered in Guam to dispense or conduct research on Cannabis. A practitioner registered under Federal law to conduct research with a substance included in Schedule I may conduct research with the substance in Guam upon furnishing DPHSS evidence of the Federal registration.

(c) A reverse distributor or reverse processor must be registered with DEA and DPHSS before receiving controlled substances acquired from another DEA and CSR registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or where necessary, processing such substances or arranging for processing such substances for disposal.

(1) The registration and other requirements for reverse distributors or reverse processors shall be the same as those currently imposed on distributors, to include but not limited to, accountability, security, inventory, recordkeeping, and reporting requirements.

(d) Upon approval by DPHSS, the registrant shall receive a Guam Controlled Substances Registration certificate that shall state:

(1) Name of the registrant;

(2) Controlled substance schedules the registrant is authorized to handle;

(3) Physical location of the principal place of business/practice, and mailing address if different from the physical address;

(4) Guam Controlled Substances Registration number, as provided by DPHSS, and its expiration date;

(5) Signature of the Director; and

(6) Other applicable information determined by the Director.

(e) Registrant shall post the Guam CSR certificate at the physical location of practice or business where an authorized inspector, as designated by DPHSS, will be able to inspect the certificate.

(f) The Director may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest.

§41606. Separate Registrations for Separate Locations, and Transfer of Locations.

(a) A separate registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed by a person or business.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed.

(1) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised, but which neither contains such substances nor serves as a distribution point for filling sales orders; and

(2) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise

dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained; and

(3) A warehouse where controlled substances are stored by or on behalf of the registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to a person not required to register by virtue of the Guam Uniform Controlled Substances Act.

(c) A registrant who intends to move his place of practice or business must request a modification of his Guam CSR certificate. The request must be made in writing and approved prior to the effective date of the move. If any registrant moves his place of business or practice without requesting and obtaining prior approval in the form of a modification of his Guam CSR certificate by DPHSS, then his registration shall automatically become invalid regardless of the expiration date.

§41607. Application.

(a) Any practitioner who is required to be registered and who is not so registered may apply for registration at any time. No practitioner required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a CSR is issued by the Director to such person.

(b) Interested persons may pick up the application for CSR at the Division of Environmental Health of DPHSS or may request the application to be mailed.

(c) The application shall state the following:

(1) Name of applicant;

(2) Name of business or practice;

(3) Physical and mailing address of business or practice;

(4) Telephone and facsimile numbers;

(5) Schedule(s) of controlled substances utilized;

(6) Licensed profession; and

(7) Any other information, or materials, deemed necessary by DPHSS, including but not limited to, any surrender, suspension, or revocation of controlled substances privileges from the DEA or DPHSS, or from any other state or federal agency, and any conviction record involving any controlled substances at any time and under any law governing the same.

(d) Renewal application for CSR will be mailed to the address indicated on the registrant's last application at least sixty (60) days prior to the date of expiration. Any registrant not receiving the renewal application 45 days prior to date of expiration should immediately notify DPHSS.

(f) Any person who is registered may apply for a renewal, provided it is not more than 60 days from the expiration date stated on his CSR.

(g) Any person applying for a renewal after 30 days or more from the expiration date stated on his CSR shall be considered a new applicant.

§41608. Filing of Application.

(a) All applications shall be delivered to the Division of Environmental Health of the Department of Public Health in Mangilao or mailed to the Division of Environmental Health, the Department of Public Health and Social Services, 123 Chalan Kareta Mangilao, Guam 96913-

6304.

(b) The post-marked date shall be considered the date of receipt by DPHSS for all applications received by mail. The date of acknowledged payment for application shall be considered the date of receipt by DPHSS for all other applications not received by mail.

(c) Only the original, complete application with appropriate payment shall be accepted and processed. Any photocopy, incomplete or illegible application, or any application not written in indelible ink, or missing a required document or payment, shall not be processed and shall be returned via mail.

§41609. Additional Information.

(a) DPHSS may require an applicant to submit such documents or written statements of fact as DPHSS deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within ten working days after being requested to do so shall be deemed a waiver by the applicant to present such documents or facts for consideration by DPHSS in granting or denying the application.

(b) All registrants applying for the Guam Controlled Substances Registration with DPHSS, or already registered with DPHSS, must provide a copy of their most recent DEA Controlled Substances Registration Certificate (federal registration) once that certificate becomes available to the registrant.

§41610. Amendments to and Withdrawals of Applications.

An application may be amended or withdrawn without permission of DPHSS at any time before the applicant receives an order to show cause pursuant to the Act. An application may be amended or withdrawn as a matter of course due to a change in the applicant's federal controlled

substances status or registration.

§41611. Fee Amounts.

(a) For each initial Controlled Substances Registration:

(1) To manufacture controlled substances, the applicant shall pay a fee of **One Thousand Dollars ($1000).**

(2) To distribute controlled substances, the applicant shall pay a fee of **Five Hundred Dollars ($500).**

(3) To dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants shall pay a fee of **Five Hundred Dollars ($500),** and a pharmacy shall pay a fee of **Five Hundred Dollars ($500).**

(b) For each renewal of Controlled Substances Registration:

(1) To manufacture controlled substances, the registrant shall pay fee of **One Thousand Dollars ($1000).**

(2) To distribute controlled substances, the registrant shall pay fee of **Five Hundred Dollars ($500).**

(3) For each renewal registration to dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants shall pay a fee of **Five Hundred Dollars ($500),** and pharmacy shall pay a fee of **Five Hundred Dollars ($500).**

(c) Any registrant who submits its renewal application thirty days after the expiration date shall be considered a new applicant and shall pay the required initial fee.

(d) Any registrant who has a current CSR and is required to correct or update such CSR due to change of address or any other reasons requiring the re-issuance of another CSR, shall pay a fee of Ten Dollars ($10.00).

(e) Registration and renewal fees shall be paid at the time when application for registration or renewal is submitted for filing. Payment shall be made in the form of a certified or cashier's check, money order, or personal or business check drawn through a locally existing bank. Initial application and renewal application fees are non-refundable.

§41612. Persons Exempt from Fee.

(a) Department of Public Health and Social Services shall exempt from payment of a fee for registration or renewal any official, employee, or entity of DPHSS who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense such substances, to conduct research and instructional activities or chemical analysis with such substances or any combination thereof in the course of his or its official duties or employment.

(b) Department of Public Health and Social Services shall exempt from payment of a fee for registration or renewal any official, employee, or entity of a law enforcement agency laboratory, including laboratories of the DEA, which is authorized to obtain and transfer controlled substances for use as standards in chemical analysis, Guam Police Forensic Laboratory, who or which is authorized under the Attorney General of Guam or the Judiciary of Guam to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this subchapter. The Attorney General of Guam may authorize an official, employee, or entity to

possess controlled substances, by obtaining such substances from investigations, examination of scenes of crime, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court, and to conduct research or chemical analysis with such substances or any combination thereof in the course of his or its official duties or employment. Such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration.

(c) In order to claim exemption from payment of a registration or renewal fee, the registrant shall submit a statement wherein the registrant's supervising officer certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or otherwise be permitted to handle controlled substances.

(d) Exemption from payment of a registration or renewal fee does not exempt the registrant from any other requirements or duties prescribed by law.

§41613. Exemption of Agents and Employees; Affiliated Practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment.

(b) Practitioner (including an intern, resident or foreign physician) who is an employee of a registered hospital or clinic may dispense controlled substances under that hospital's or clinic's registration provided that:

(1) Such dispensing is done in the usual course of his professional practice as an employee of the institution;

(2) Such employed practitioner is authorized or permitted to do so by the laws of Guam;

(3) The hospital or the institution has verified that the practitioner is so permitted to dispense, administer, or prescribe controlled substances in Guam;

(4) Such practitioner is acting only within the scope of his employment in the hospital or institution;

(5) The hospital or the institution authorizes the practitioner to dispense under the institution's registration and designates a specific internal code number for each practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the hospital's or institution's Guam CSR number, preceded by a hyphen (ex: HOO1-01 or COO1-A1); and

(6) The hospital or the institution provides a current list of internal codes with corresponding individual practitioners to DPHSS, and is made available at all times to pharmacies registered with the Department and law enforcement agencies upon request for the purpose of verifying the authority of the administering, dispensing, and prescribing practitioner.

§41614. Exemption of Certain Military and Other Personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, U.S. Navy, U.S. Marine Corp., U.S. Air Force, U.S. Coast Guard, and U.S. Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase controlled substances in the course of his official duties. Prescriptions written by persons mentioned in this section may be honored by a pharmacy outside the military installation, if so

desired by the pharmacist, provided that:

(1) Pharmacist makes a reasonable effort to determine that the prescription is legitimate, which may include a call back to the prescriber, and/or other good faith efforts to insure the identity; and

(2) The prescription has the branch of service/agency, service identification of practitioner, practitioner's and patient's name and address, date, and instructions.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities and pay the required fee.

§41615. Exemption of Law Enforcement Officials.

(a) The requirement of registration is waived for the following persons in circumstances described in this section:

(1) Any officer or employee of a Government of Guam agency who is engaged in the enforcement of any Guam law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(2) Any officer or employee of the United States DEA, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties, including personnel in the investigative services of the military forces stationed on Guam.

(3) Any officer or employee of Guam, or any political subdivision or agency

thereof, who is engaged in the enforcement of any Guam law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.

(4) Any official exempted by this section may, when acting in the course of his official duties, possess a controlled substance and distribute such substance to any other official exempted by this section and acting in the course of his official duties.

(5) Any official exempted by this section may procure a controlled substance in the course of an inspection, in accordance with the Act, or in the course of any criminal investigation involving the person from whom the substance was procured.

(6) In order to enable law enforcement agency laboratories, including laboratories of the DEA, to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in section 515(d) of the federal Controlled Substances Act (21 U.S.C. 885(d)). For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

(7) In addition to the activities authorized under a registration to conduct chemical analysis pursuant to Title 21 of the Code of Federal Regulations, Part 1301, §1301.13(e)(1)(ix), laboratories of the DEA shall be authorized to manufacture or import controlled substances for any lawful purpose, to distribute or export such substances to any

person, and to import and export such substances in emergencies without regard to the requirements of Title 21 of the Code of Federal Regulations, Part 1312 if a report concerning the importation or exportation is made to the Drug Operations Section of the DEA within 30 days of such importation or exportation.

§41616. Exemption of Civil Defense Officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is in accordance with applicable local and federal laws governing controlled substances and any emergency preparedness plans of Civil Defense.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization within his jurisdiction proclaimed by the Governor or by a concurrent resolution of the Guam Legislature or by the Civil Defense network on Guam, which official, in the course of his official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on the official form provided by Civil Defense.

(c) Such forms may be used and are valid only during a state of emergency or disaster in which the organization using such forms has civil defense or disaster relief

jurisdiction, and which shall state the position of the user and the nature and legal designation of the emergency or disaster. Any person registered under the Act may complete such forms. The organization using civil defense emergency order forms will be deemed to be registered under the Act for purposes of record keeping.

§41617. Administrative Review Generally.

DPHSS may inspect or cause to be inspected the establishment of an applicant or registrant, pursuant to the Act. DPHSS shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of the Act have been met by the applicant.

§41618. Certificate of Registration.

DPHSS shall issue a certificate of registration to an applicant if the issuance of registration or renewal is required under the applicable provisions of the Act. In the event that the issuance of registration or renewal is not appropriate, DPHSS shall deny or refuse the application. Before denying or refusing any application, DPHSS shall issue an order to show cause pursuant to these rules. If requested by the applicant, DPHSS shall hold a hearing on the application pursuant to these rules and the Administrative Adjudication Law.

§41619. Suspension or Revocation of Registration.

(a) DPHSS may suspend any registration pursuant to the Act for any reasonable and justifiable period of time as determined by DPHSS.

(b) DPHSS may revoke any registration pursuant to the Act.

(c) Before revoking or suspending any registration, DPHSS shall issue an order to show cause pursuant to the Act and, if requested by the registrant, shall hold a hearing pursuant to

the Act and the Administrative Adjudication Law. Notwithstanding the requirements of this section, however, DPHSS may suspend any registration pending a final order pursuant to these rules.

(d) Upon service of the order of DPHSS suspending or revoking registration, the registrant shall immediately surrender his certificate of registration to DPHSS. In addition, the registrant, as instructed by DPHSS, shall deliver all controlled substances in his possession to DPHSS for destruction.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by such revocation or suspension. No fees shall be required to be paid for the new certificate. The registrant shall surrender the old certificate of registration to DPHSS. In addition, the registrant shall, as instructed by DPHSS, deliver to DPHSS, or to authorized agents, all of the particular controlled substance or substances affected by the revocation or suspension that are in his possession for destruction.

§41620. Suspension of Registration Pending Final Order.

(a) DPHSS may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where DPHSS finds that there is an imminent danger to the public health or safety. If DPHSS so suspends, DPHSS shall serve with the order to show cause pursuant to the Act an order of immediate suspension which shall contain the statement of DPHSS' findings regarding the danger to the public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly

surrender his certificate of registration to DPHSS. Also, upon service of the order of DPHSS immediately suspending registration, the registrant shall, as instructed by DPHSS, deliver all affected controlled substances in his possession to DPHSS or his authorized agents or place all such substances under seal as prescribed by the Act.

(c) All suspensions shall continue in effect until the conclusion of all proceedings in the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by DPHSS or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause, which request may be granted by DPHSS, who shall fix the date for such hearing as early as reasonably possible.

§41621. Extension of Registration Pending Final Order.

In the event that an applicant for renewal (who is doing business under a registration previously granted and not revoked or suspended) has applied for renewal at least 30 calendar days before the date on which the existing registration is due to expire, and DPHSS has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be renewed and continued in effect until the date on which DPHSS, if and when, issues the order.

§41622. Order to Show Cause.

(a) If, upon examination of the application for registration from an applicant and other information regarding that applicant, DPHSS is unable to make the determination by the applicable provisions of the Act to register the applicant, or decides to deny the application,

DPHSS shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information regarding any registrant, DPHSS determines that the registration of such registrant is subject to suspension or revocation pursuant to the Act, DPHSS shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the registrant to appear before the DPHSS at a time and place stated in the order, which shall not be less than thirty (30) calendar days after the date of receipt of the order. This order to show cause shall also contain the statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for hearing pursuant to the Administrative Adjudication Law. If hearing is requested, DPHSS shall hold a hearing at the time and place stated in the order, pursuant to these rules regarding hearings.

(e) When authorized by these rules and the Act, any agent of DPHSS may serve the order to show cause.

(f) If the registrant or applicant does not request a hearing within the time limit as stated in the Administrative Adjudication Law, then DPHSS may proceed as provided by law.

§41623. Hearings Generally.

(a) In a case where DPHSS shall hold a hearing on any registration or application, the procedures for such hearings shall be governed by the Administrative Adjudication Law.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or under any other law of Guam.

§41624. Response to Order to Show Cause.

(a) After the filing of and service upon the registrant of an order to show cause, the registrant has fifteen (15) calendar days after service of the order in which to reply. The registrant may:

(1) Request a hearing.

(2) Object to the order upon the ground that it does not state the act or omissions upon which DPHSS may proceed to take action as stated in the order.

(3) Object to the form of the accusation on the grounds that it is so indefinite or uncertain that he cannot identify the allegations for preparative defense.

(4) Admit to the accusation in whole or in part.

(5) Prepare and submit new matter by way of his defense.

§41625. Request for Hearing.

A simple request for a hearing shall be deemed a specific denial of all parts of the accusation contained within the order to show cause, which are not expressly admitted. Said notice of defense shall be in writing signed by or on behalf of the applicant or registrant and shall state his mailing address and physical address, if different.

§41626. Filing of Response.

The registrant or applicant shall file his response to the order not more than fifteen (15) calendar days after the service of the order upon him.

§41627. Failure to File a Notice.

A failure to file a notice of defense or any notice indicating that the applicant or registrant desires a hearing and will appear upon the date stated in the order to show cause shall constitute a waiver of the applicant or registrant's right to a hearing, but DPHSS at its discretion may grant a hearing.

§41628. Notice.

DPHSS shall include with the order to show cause served upon the applicant or registrant a notice of defense entitled as such which may be in any form satisfactory to DPHSS. Also, DPHSS shall include a notice stating that the applicant or registrant waives a hearing unless a reply is received requesting the same or stating defense or defenses to the order within the time limit as stated below of these rules. This notice shall be in substantially the form: *'Unless notice, signed by or on behalf of the applicant or registrant, is delivered or mailed to the Director within fifteen (15) calendar days after receipt of the order to show cause or, at least, not less than ten (10) calendar days prior to the hearing date as stated in the order to show cause, the Director of the Department of Public Health and Social Services may proceed upon the order without a hearing. The notice of the hearing may be delivered or mailed by using the enclosed form, or any other notice of similar intent, to the Director of the Department of Public Health and Social Services, Government of Guam, Hagatna, Guam, or by personal delivery to the office of the Director, Department of Public Health and Social Services, Mangilao.'*

§41629. Serving of Order to Show Cause.

Service of the order to show cause may be made by any person so delegated by DPHSS by personally serving the applicant or registrant or by sending the order to show cause by registered mail to the last known address of the applicant or registrant as contained within his

application or registration files, or by leaving a copy of the order and accompanying papers at his usual place of residence or business with some person of suitable age and discretion residing or working therein.

§41630. Serving of Other Materials.

All other papers required to be served upon the applicant or registrant may be served in the manner of the order.

§41631. Amended or Supplemental Orders.

At any time before the matter is submitted for a decision, DPHSS may file or permit the filing of amended or supplemental orders. All parties shall be notified if this occurs. If the amended or supplemental orders present new charges, DPHSS shall afford the applicant or registrant a reasonable opportunity to prepare his defense thereto. Unless DPHSS orders in the individual case, the applicant or registrant shall not be entitled to further pleading. New charges shall be deemed controverted and any objections to the amended or supplemental order may be made orally and shall be noted on the record.

§41632. Time and Place of Hearing.

The time and place of the hearing shall be as stated on the order to show cause.

§41633. Order to Show Cause Form.

The order to show cause shall be in substantially the following form, but may include any other information and the charges:

GOVERNMENT OF GUAM

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES

IN RE THE APPLICATION OF)

(Applicant) under the Uniform Controlled Substances Act	*ORDER TO SHOW CAUSE*

You, (name of applicant or registrant) are hereby commanded to appear before the Director of the Department of Public Health and Social Services or his delegate on_____ day of_____, _____and show cause as to why your (application or registration) under the Uniform Controlled Substances Act should not be (denied, suspended, or revoked) for the following reasons:

1. (here follows a list of the specifications and reasons for such denial, suspension or revocation).

You may submit to the Director at the following address:

Director of the Department of Public Health and Social Services Government of Guam
123 Chalan Kareta
Mangilao, Guam 96913-6304

or

Office of the Director
Department of the Public Health and Social Services
Mangilao, Guam
or their succeeding addresses

a notice that you intend to appear before the Director or his delegate at the hearing scheduled on the above date. You may also submit to the Director any objections or defenses which you might have within 15 days of the time this notice was served upon you or at least, then (10) days prior to the date of the hearing. If you fail to submit any notice or objections or defenses, then it will be assumed that you have waived your right to a hearing and the Director or his delegate may proceed to a decision in your case at or after the date and time for the hearing set forth above. Date this (month) and (year).

Director of the Department Public Health and Social Services

By (delegate)

§41634. Subpoena.

Before the hearing has commenced, DPHSS shall issue subpoena and subpoena *duces tecum* at the request of any party in accordance with the provisions of Section 1985 of the Code of Civil Procedure. After the hearing has commenced, the Director or hearing officer sitting alone may issue such subpoena and subpoena *duces tecum* as he deems necessary.

§41635. Depositions.

Upon the verified petition of any party, DPHSS may order that the testimony of any material witness residing within or outside the island of Guam be taken by deposition in the manner prescribed by law for depositions in civil actions. The petition shall set forth the nature of the pending proceedings, the name and address of the witness whose testimony is desired, a showing of the necessity of his testimony, a showing that the witness would be unable or cannot be compelled to be present; and shall request an order requiring the witness to appear and testify before an officer named in the petition for that purpose. Where the witness resides outside

of Guam and where the agency has ordered the taking of his testimony by deposition, the agency shall obtain an order of court to that effect by filing a petition therefor in the District Court of Guam.

§41636. Power to Administer Oaths and Affirmations by DPHSS.

In any proceedings under the order to show cause or any other hearing provided for by the Act, the Director of the Department of Public Health and Social Services, or any of his duly authorized representatives, have the power to administer oaths and affirmations and to certify to official acts.

§41637. Hearing Officer.

A hearing officer shall preside over every hearing in a contested case. Said person shall be an attorney and may be an attorney in the full-time service of the government. DPHSS may request the Attorney General of Guam to assign a member of his staff as hearing officer for the case, provided that the attorney has had no prior connection with the matters involved in the hearing. The case may be heard by the agency with a hearing officer or by a hearing officer alone, in the discretion of DPHSS. The hearing officer shall preside in any event, rule upon the admission and exclusion of evidence and advise the agency on matters of law. Where the agency is holding the hearing, it shall exercise all of the powers relating to the conduct of a hearing but may delegate any or all of them to the hearing officer. Where the hearing officer alone hears the case, he shall exercise all powers relating to the conduct of the hearing.

§41638. Disqualification.

A hearing officer or member of DPHSS shall voluntarily disqualify himself and withdraw from any case in which he cannot accord a fair and impartial hearing or consideration. Any

party may request the disqualification of any hearing officer or member of the department by filing an affidavit prior to the taking of evidence at a hearing, stating with particularity the grounds upon which it is claimed that a fair and impartial hearing may not be accorded. Where the request concerns an agency member, the Director of DPHSS shall determine the issue. Should the disqualification prevent the existence of a quorum qualified to act in a particular case, the DPHSS member shall not withdraw voluntarily nor be subject to disqualification.

§41639. Granting of Continuance.

DPHSS may grant continuances at any stage of the proceeding, the need of which shall be determined by the hearing officer.

§41640. Evidences and Witnesses.

Oral evidence shall be taken only upon oath or affirmation. Each party shall have the right to call and examine witnesses, to introduce exhibits, to cross-examine opposing witnesses on any matter relevant to the issues even though the matter was not covered in the direct examination, to impeach any witness regardless of which party first called him to testify and to rebut the evidence against him. If the respondent does not testify in his own behalf, he may be called and examined as if under cross-examination.

§41641. Admission of Relevant Evidence.

This hearing need not be conducted according to the rules relating to evidence and witnesses. Any relevant evidence shall be admitted if it is evidence which responsible persons are accustomed to rely upon in the conduct of serious affairs, regardless of the existence of any common law or statutory rules which might make improper the admission of such evidence over objection in civil actions. Hearsay evidence may be used to supplement or explain

direct evidence but shall not be sufficient by and of itself to support a finding, unless it would be effective to the same extent as recognized in civil actions. Irrelevant and unduly repetitive evidence may be excluded.

§41642. Matter not covered in Administrative Adjudication Law and Uniform Controlled Substances Act.

Any matter not covered by these rules and regulations, the Administrative Adjudication Law or by the Uniform Controlled Substances Act, shall be decided by the agency or hearing officer before whom the matter was presented.

§41643. Security Requirements Generally.

(a) All applicants and registrants shall provide effective controls and procedures to deter and guard against theft and diversion of controlled substances. Whether a registrant has provided effective controls against diversion shall be determined by DPHSS using the requirements set forth in these rules and the Act.

(b) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in these rules when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business

operations.

§41644. Physical Security for all Registrants.

Persons registered under this Act shall maintain security in conformance with the security requirements of Federal law and accordance to other requirements stated in these rules.

§41645. Security for Pharmacies.

All pharmacies dispensing controlled substances in Schedules II through *N* shall be equipped with an alarm within its premises which shall transmit a signal directly to a central station protection company or the Guam Police Department, or a 24-hour control station operated by the registrant. An exemption to this section may be granted by the DPHSS to a pharmacy if the establishment can provide reasonable justification, in writing, for not installing such system.

§41646. Increase in Security Requirements.

(a) In evaluating the overall security system of a registrant, DPHSS may consider, but is not limited to, any of the following factors as DPHSS may deem relevant to the need for stricter compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, schedule, usable powders or non-usable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on

security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems;

(9) The adequacy of electric detection and alarm systems and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel; and

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

§41647. Inspection: How often, Authority, and Consent.

(a) DPHSS may make administrative inspections of registered establishments or activity

based upon administrative probable cause. Such warrant shall be issued upon the affidavit of duly authorized persons and sworn to before a judge of the Superior Court of Guam, pursuant to the Act.

(b) An inspection, through the use of administrative warrant, shall be carried out by a DPHSS employee duly authorized by the Director of DPHSS. Any such inspector, upon stating his purpose and presenting to the owner, operator or agent in charge of the premises to be inspected his appropriate credentials, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

(c) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected. Informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected. The written consent shall contain the following information:

(1) That he (the owner, operator, or agent in charge of the premise) has been informed of his constitutional right not to have an administrative inspection made without an administrative inspection warrant;

(2) That he has the right to refuse to consent to such an inspection;

(3) That the consent given by him is voluntary and without threats of any kind; and

(4) That he may withdraw his consent anytime during the inspection.

(d) The written consent shall be produced in duplicate with the original retained by the inspector, and the duplicate to be given to the person inspected.

§41648. Prescription Information.

All prescriptions for controlled substances shall provide the information mandated by Federal law and any other requirements stated elsewhere in these rules and the Act.

§41649. Printing and Signing of Prescription.

Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.

§41650. Identification.

Upon receipt of a prescription for controlled substance, a pharmacist must verify the identification of that person to whom the prescription is written for by examining his valid and current picture identification. Valid and current picture identification shall be an official:

(a) Government of Guam Identification Card;

(b) Passport;

(c) Guam Driver's license;

(d) Military identification card; or

(e) Any other legal picture identification the Director deems acceptable.

§41651. Submitting of Prescription by Third Party.

In the event a prescription for controlled substance is brought to a pharmacy by an individual other than the person the prescription is written for, the pharmacist shall verify the identification of that individual before the order is filled, and the pharmacist shall print on the back of that prescription:

(a) The individual's name; and

(b) The individual's identification number.

§41652. Acquisition of Signature.

Prior to the actual dispensing of a controlled substance, a pharmacist must obtain a signature of the individual submitting a prescription for controlled substances listed in Schedules II, ill, and IV. The signature shall be written on the back of the prescription.

§41653. Effective Date.

These rules shall be effective after ninety (90) calendar days have elapsed from the dated of filing with the Legislative Secretary. At that time, all other rules and regulations or parts of other rules and regulations that conflict with these rules are repealed.

§41654. Severability.

If any provision or application of any provision of these rules is held invalid, that invalidity shall not affect the other provisions or applications of these rules."

PUBLIC HEARING TRANSCRIBED ORAL TESTIMONIES

MINUTES OF PUBLIC HEARING
Proposed Rules and Regulations
Governing the Manufacture, Distribution, and Dispensing of Controlled Substances
June 26, 2015 (4:30 p.m. – 6:00 p.m.)
PHICC, Conference Room
Central Public Health Facility, Mangilao

TOPICS	DISCUSSIONS	REMARKS AND ACTIONS TO BE TAKEN
I. Attendance	There were 3 representatives from the Department of Public Health and Social Services (Division of Environmental Health) present.	DEH Representative Present: Rosanna Rabago, EPHO Administrator Cynthia Naval, Planner IV Michelle Lastimoza, EPHO III
II. Opening Remarks		Hafa Adai. It is now 3:00 PM, on May 15, 2015. My name is Rosanna Y. Rabago; I am an Environmental Public Health Officer Administrator with the Division of Environmental Health of the Guam Department of Public Health and Social Services. On behalf of the Director of this Department, Mr. James Gillan, we welcome you all to this public hearing where we will be accepting and hearing comments on the proposed *Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances.* With me today is Ms. Michelle Lastimoza and Katherine Duenas, Environmental Public Health Officers with Division of Environmental Health and Ms. Cynthia Naval, Planner IV also with the Division. The promulgation of rules and regulations is governed by the Administrative Adjudication Law (AAL; Title 5, Chapter 9, Guam Code Annotated), and Section 9301 of that law requires that 10 days before the public hearing, a notice must appear in the newspaper of general circulation in Guam announcing the date, time, and place of the public hearing. The Department did comply with that provision by publishing the announcement in the *Marianas Variety* on May 1, 2015. The Department

		published a second announcement on May 14, 2015. As part of the AAL procedures, it was determined by the Department that these proposed rules are exempted from the requirements of an Economic Impact Statement because the annual economic impact to the general public will be less than five hundred thousand dollars. Title 9 GCA, Chapter 67 mandates the Division of Environmental Health to regulate and control the manufacture, distribution, and dispensing of controlled substances in Guam. To carry out the provisions of this mandate, Section 67.301(a) of Title 9 GCA, Chapter 67 authorizes the Director of the Department of Public Health and Social Services to adopt rules and charge fees to administer the Controlled Substances Program. The last time these rules were updated was four years ago in 2011. With the rise in popularity of pharmaceutical controlled substance abuse and diversion, the Division of Environmental Health has seen a significant increase in the number of suspect violations of the Act, including having to bear the additional costs of implementing programs for prescription drug monitoring and medical marijuana. These costs, coupled with the need to conduct training for law enforcement officers, healthcare practitioners, and the public has created a burden on DEH. The increased fee schedule will assist DEH in ensuring that dedicated staff be recruited and assigned to the Controlled Substances Program. We will now formally accept any written or oral testimonies on the proposed *Rules Governing the*

		Manufacture, Distribution, and Dispensing of Controlled Substances. Dangkolo Na Si Yu'os Ma'ase!
III. Written or Oral Testimonies	There were no written or oral testimony given.	There were no public participants during the the public hearing today. The public was adjourned at 6:00 p.m. by Ms. Michelle Lastimoza.

LETTER RE: GUIDANCE FOR FORMATTING RULES AND REGULATIONS

Guam Law Library, 141 San Ramon Rd., Hagåtña, Guam 96910-5174
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F. PHILIP CARBULLIDO
Chief Justice

GERALDINE AMPARO CEPEDA
Compiler of Laws

GUIDANCE FOR FORMATTING RULES AND REGULATIONS (GAR)

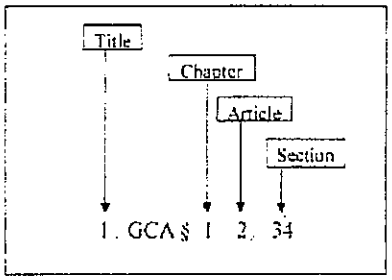
The Office of the Compiler of Laws is statutorily mandated to "[u]ndertake the publication of the continuing Administrative Rules and Regulations" of Guam. 1 GCA § 1602(c). The authority for the rule-making procedures of government of Guam agencies, departments, and other entities are set forth in Title 5, Guam Code Annotated, Chapter 9, Article 3, entitled "Rule-making Procedures." As part of this process, the rules are statutorily required to be "in a form approved by the Compiler of Laws." 5 GCA § 9303(a).

To assist government of Guam agencies, departments, and other entities, with the process of publishing submissions for including in the Guam Administrative Rules & Regulations (GAR), the Office of the Compiler of Laws has prepared this document to give guidance in the drafting process. It is strongly encouraged that those responsible for drafting rules and regulations review the recommendations and utilize the standard format herein, which was approved by the Guam Code Advisory Commission on June 21, 2005. Compliance with the recommended format will be de facto indication that that the submission is in a format approved by the Compiler of Laws.

Recommendation 1
Please compose GAR sections according to the diagram below. It is helpful to know that the GAR is divided into the following subdivisions in descending order:

Title (mandatory)
Division (if necessary)
Part (if necessary)
Chapter (mandatory)
Article (if necessary)
Section (mandatory)
Subsection (if necessary)

Note that Title, Chapter and Section designations are required for any codification scheme. Division, Part and Article designations are sometimes not used in particular codification schemes. We recommend that whenever possible, Article designations be used. The following diagram shows an example of the general codification scheme for the GCA, which similarly applies to the GAR:



Recommendation 2

Please draft GAR sections according the example below and identify subsections in the following format.

§ 1101. Name or Title of Section.

In the section title, the first letter of each major word is capitalized. Do not capitalize minor words such as conjunctions and articles (e.g. and, but, or, the, a, etc.). The text of the section should be written as shown in this example.

(a) First subsection. The first subsection (if any) is designated with small letters in parentheses.

(1) Second subsection. The second subsection (if any) is designated by Arabic numerals in parentheses.

(A) Third subsection. The third subsection (if any) is designated by large capital letters in parentheses.

(i) Fourth subsection. The fourth subsection (if any) is designated by small Roman numerals in parentheses.

(aa) Fifth subsection. If necessary, a fifth subsection is designated by double lower case letters in parentheses and the cycle repeats as follows.

(1) Sixth subsection.

(AA) Seventh subsection.

(i) Eighth subsection.

Recommendation 3

Please use Microsoft Word for creating new legislative documents. The Compiler's Office now uses Microsoft Word exclusively for processing the GAR. Legal publishers such as Lexis and West require transmittal of Word files. Use of MS Word will minimize glitches and errors caused by conversions of files created with other word processing software such as WordPerfect.

Recommendation 4
Please use Times New Roman font in documents. Times New Roman seems to be used universally and is a true-type font necessary for embedding in documents to be published. We use this font exclusively in all GAR documents.

Recommendation 5
When assigning a code section number to a new statutory addition and you are unsure of whether the desired code section number is vacant and available, please call our office.

Thank you for considering these recommendations. Please note that the suggestions herein are not necessarily hard and fast rules. There may be occasions requiring deviation from any standard formatting scheme. If you have any questions or comments, please do not hesitate to call my office.

GERALDINE A. CEPEDA