

Office of the Governor of Guahan

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Felix P. Camacho Governor

Michael W. Cruz. M.D. Lieutenant Governor

The Honorable Judith T. Won Pat, Ed.D. Speaker *Mina' Trenta Na Liheslaturan Guåhan* 155 Hessler Street Hagåtña, Guam 96910

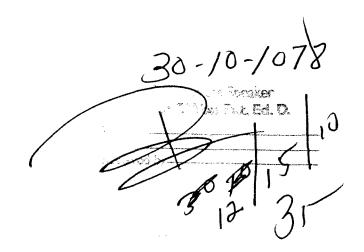
*Hafa Adai!* Pursuant to §3131, Division 1, Chapter 3 of Title 5 GCA, the Department of Public Health and Social Services submits its proposed amendments to the existing rules governing the manufacture, distribution and dispensing of controlled substances on Guahan. The proposed rules seek to revise the current fee schedule to reflect the actual cost incurred by the department in issuing the Guam Controlled Substances registrations to our island's practitioners and institutions.

Should you have any questions regarding this matter, please contact Mr. J. Peter Roberto, ACSW, the Director of the Department of Public Health and Social Services, at 735-7101.

Sinseru yan Magåhet, an

**FELIX P. CAMACHO** *I Maga'lahen Guahan* Governor of Guahan

Enclosures





## GOVERNMENT OF GUÅHAN

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

123 Chalan Kareta, Mangilao, Guåhan 96913-6304

OV 1 9 2010



Felix P. Camacho Governor

Michael W. Cruz, M.D. Lieutenant Governor J. Peter Roberto, A.C.S.W. Acting Director

OFFICE OF THE GOVERNOR NOV 2 3 2010

DATE

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TO: Governor of Guåhan 🔪

- ATTN: Mr. Ray C. Haddock, Esq. Assistant Legal Counsel
- FROM: Acting Director, Department of Public Health and Social Services
- SUBJECT: Proposed Repeal and Re-enactment of the Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances

*Hafa Adai!* Pursuant to §3131, Division 1, Chapter 3 of Title 5 GCA, the Division of Environmental Health (DEH) of this Department held a public hearing to receive public comments on the division's proposed amendments to the "Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances." The hearing was held on February 16, 2010 from 4:00 p.m. to 5:00 p.m. at the Castle Mall, Mangilao. The most notable change to the rules is the increase in the fee schedule, which reflects the cost incurred by the department to issue the Guam Controlled Substances Registration to the practitioners and institutions that handle (pharmaceutical) controlled substances on Guam. The proposal has been reviewed by Mr. Ray Haddock and the necessary revisions have been made to the document.

The procedures provided in the Administrative Adjudication Law (Title 5 GCA Chapter 9, Article 3) were followed in notifying and conducting the public hearing. A notice of public hearing was announced in the local newspaper on February 5, 2010 and February 15, 2010.

As provided in §9301(i) of Article 3, Chapter 9 of Title 5 GCA, an Economic Impact Statement was not prepared for the proposed fee change for the issuance of GCSR since the anticipated impact would be less than \$500,000. No oral or written testimony was received from the public for the proposed fee increase. We have attached the following materials:

• Public hearing notices that were printed in the Marianas Variety on February 5, 2010 and February 15, 2010;

Telephone No.: 1.671.735.7102 \* Fax No.: 1.671.734.5910

- Proposed "Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances" with noted amendments;
- Minutes of the February 16, 2010 public hearing;
- Draft transmittance letter to Legislative Secretary Tina Muna-Barnes of the 30<sup>th</sup> Guam Legislature; and
- CD with electronic copy of the attached regulations and the draft transmittance letter to the Legislative Secretary, Senator Tina Muna-Barnes.

For any questions you may have in this matter, please contact Mr. M. Thomas Nadeau, the Administrator of the Division of Environmental Health, at 735-7221/7209. Dangkolo Na Si Yu'os Ma'ase!

J. PETER ROBERTO, ACSW

Attachments

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- nearly always the mother - set Japan apart from most other developed countries. They also leave most fathers, including foreigners, unable to see their children until they are grown.

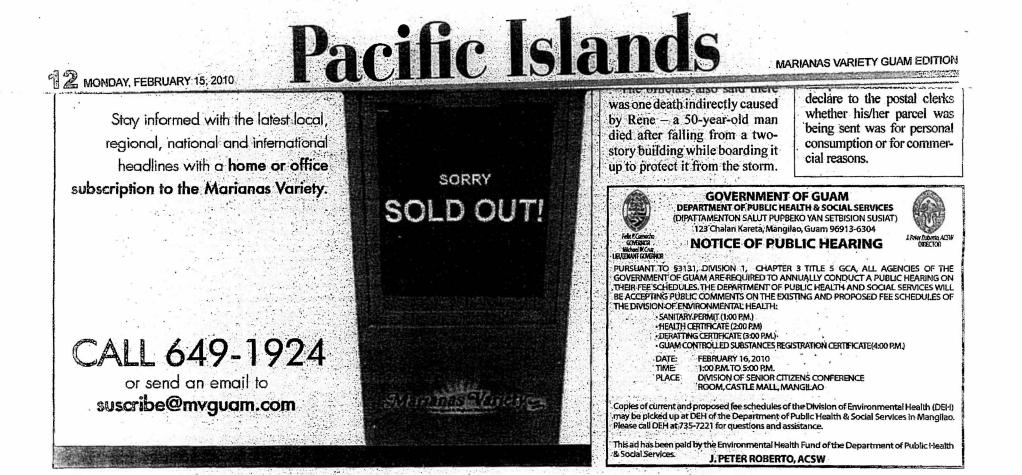
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Thai soldiers carry the flags of participating nations who have joined forces for on annual combined military exercise in Rayong province, Thailand. The Rayong province, Utaliand. The U.S. military has begun its largest war games in the Pochc region -

An annual fraining exercise with

# Pon't miss another issue of





1	Title 26 Guam Administrative Rules and Regulations, Chapter 4, "Rules Governing the
2	Manufacture, Distribution, and Dispensing of Controlled Substances" is hereby repealed in
3	its entirety and re-enacted to read as follows:
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5	
6	
7	
8	<b>"RULES GOVERNING THE</b>
9	MANUFACTURE, DISTRIBUTION, AND
10	DISPENSING OF CONTROLLED
11	SUBSTANCES
12	
13	DIVISION OF ENVIRONMENTAL HEALTH
14	DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
15	123 CHALAN KARETA
16	MANGILAO, GUAM 96910-6304
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1		Article 16
2		Rules for Pharmaceutical Controlled Substances
3		
4	§41601.	Purpose.
5	_	Authority.
6	§41603.	-
7	§41604.	Definitions.
8		Guam Controlled Substances Registration.
9		Separate Registrations for Separate Locations, and Transfer of Locations.
10		Application.
11	§41608.	Filing of Application.
12	-	Additional Information.
13	§41610.	Amendments to and Withdrawals of Applications.
14	§41611.	Fee Amounts.
15	§41612.	Persons Exempt from Fee.
16	§41613.	Exemption of Agents and Employees; Affiliated Practitioners.
17	§41614.	Exemption of Certain Military and Other Personnel.
18	§41615.	Exemption of Law Enforcement Officials.
19	§41616.	Exemption of Civil Defense Officials.
20	§41617.	Administrative Review Generally.
21	§41618.	Certificate of Registration.
22	§41619.	Suspension or Revocation and Registration.
23	§41620.	Suspension of Registration Pending Final Order.
24	§41621.	Extension of Registration Pending Final Order.
25	§41622.	Order to Show Cause.
26	§41623.	Hearings Generally.
27	§41624.	Response to Order to Show Cause.
28	§41625.	Request for Hearing.
29	§41626.	Filing of Response.
30	*	Failure to File a Notice.
31	§41628.	
32		Serving of Order to Show Cause.
33		Serving of Other Materials.
34		Amended or Supplemental Orders.
35	-	Time and Place of Hearing.
36	-	Order to Show Cause Form.
37	-	Subpoena.
38	÷	Depositions.
39		Power to Administer Oaths and Affirmation by DPHSS.
40	~	Hearing Officer.
41		Disqualification.
42	§41639.	Granting of Continuance.
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1 §41640. Evidences and Witnesses. 2 §41641. Admission of Relevant Evidence. 3 \$41642. Matter not Covered in Administrative Law and Uniform Controlled Substances Act. §41643. Security Requirements Generally. 4 §41644. Physical Security for all Registrants. 5 б §41645. Security for Pharmacies. 7 §41646. Increase in Security Requirements. 8 §41647. Inspection: How Often, Authority, and Consent. 9 §41648. Prescription Information. §41649. Printing and Signing of Prescription. 10 11 §41650. Identification. 12 §41651. Submitting of Prescription by Third Party. 13 §41652. Acquisition of Signature. 14 §41653. Effective Date. 15 §41654. Separability. 16 17 §41601. Purpose. The purpose of these rules is to regulate the lawful manufacture, 18 19 distribution, and dispensing of controlled substances through registration and control to prevent the 20 diversion of legitimately produced controlled substances into illegitimate channels. 21 22 §41602. Authority. Section 67.301 of P.L. 24-149, an Act to Repeal and Reenact Chapter 23 67 of Title 9, Guam Code Annotated, authorizes the Director to promulgate rules providing for the 24 registration and control of the manufacture, distribution, and dispensing of controlled substances 25 within Guam. 26 27 §41603. Title. These rules and regulations shall be known and cited as the Rules 28 Governing the Manufacture, Distribution, and Dispensing of Controlled Substances or the Rules 29 for Pharmaceutical Controlled Substances. 30 31 §41604. Definitions. As used in these rules: 32 33 (a) Act shall means P.L. 24-149, an Act to Repeal and Reenact Chapter 67, Title 9, Guam 34 Code Annotated, which is also known as the Uniform Controlled Substances Act. 35 36 (b) CSR shall means the Guam Controlled Substances Registration issued by the Department. 37 38 39 (c) Individual registrant shall means a physician, dentist, veterinarian, podiatrist or other 40 lawfully licensed person permitted on Guam to dispense controlled substances in the course of his 41 professional practice, but does not include an institutional registrant, a pharmacy, or a pharmacist. 42

1 (d) Institutional registrant shall means a hospital, clinic, or other lawfully licensed 2 establishment wherein dispensing of controlled substances are permitted by Guam in the course of 3 that establishment's business, but does not include a pharmacy. 4 5 (e) *Pharmacy* shall means a lawfully licensed pharmacy permitted on Guam to dispense 6 controlled substances in the course of that establishment's business. 7 8 (f) Registrant shall means any person or establishment registered pursuant to the Guam 9 Uniform Controlled Substances Act. 10 11 Unless otherwise stated in these rules, the definitions in the Act shall also be the definitions of these 12 rules and regulations. 13 14 §41605. Guam Controlled Substances Registration. (a) Every person who 15 manufactures, distributes, or dispenses any controlled substance shall annually obtain a Guam Controlled Substances Registration unless exempted by law or as otherwise exempted by these 16 rules. Only persons or institutions directly engaged in such activities are required to obtain a 17 registration. (For example, a stockholder or parent corporation of a corporation manufacturing 18 19 controlled substances are not considered directly engaged in such activities, and need not be 20 registered.) 21 22 (b) Upon approval by DPHSS, the registrant shall receive a Guam Controlled Substances 23 Registration certificate that shall state: 24 25 (1) Name of the registrant; 26 (2) Controlled substance schedules the registrant is authorized to handle; 27 (3) Physical location of the principal place of business/practice, and mailing address 28 if different from the physical address; 29 (4) Guam Controlled Substances Registration number, as provided by DPHSS, and its expiration date; 30 31 (5) Signature of the Director; and 32 (6) Other applicable information determined by the Director. 33 34 (c) 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 35 36 certificate. 37 38 §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 39 40 where controlled substances are manufactured, distributed, or dispensed by a person or business. 41 42 (b) The following locations shall be deemed not to be places where controlled substances

1	are manufactured, distributed, or dispensed.
2	
3	(1) An office used by agents of a registrant where sales of controlled substances are
4	solicited, made, or supervised, but which neither contains such substances nor serves as a
5	distribution point for filling sales orders; and
6 7	(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
8	regular part of the professional practice of the practitioner at such office, and where no
9	supplies of controlled substances are maintained; and
10	(3) A warehouse where controlled substances are stored by or on behalf of the
11	registered person, unless such substances are distributed directly from such warehouse to
12	registered locations other than the registered location from which the substances were
13	delivered or to a person not required to register by virtue of the Guam Uniform Controlled
14	Substances Act.
15	
16	(c) A registrant who intends to move his place of practice or business must request a
17	modification of his Guam CSR certificate. The request must be made in writing and approved prior
18	to the effective date of the move. If any registrant moves his place of business or practice without
19	requesting and obtaining prior approval in the form of a modification of his Guam CSR certificate
20	by DPHSS, then his registration shall automatically become invalid regardless of the expiration
21	date.
22	
23	§41607. Application. (a) Interested persons may pick up the application for CSR at the
24	Division of Environmental Health of DPHSS or may request the application to be mailed.
25	
26	(b) The application shall state the following:
27	(1) Name of applicant;
28	(2) Name of business or practice;
29	(3) Physical and mailing address of business or practice;
30	(4) Telephone and facsimile numbers;
31	(5) Schedule(s) of controlled substances utilized;
32	(6) Licensed profession; and
33	(7) Any other information, or materials, deemed necessary by DPHSS, including
34	but not limited to, any surrender, suspension, or revocation of controlled substances
35	privileges from U.S. DEA or DPHSS, or from any other state or federal agency, and any
36	conviction record involving any controlled substances at any time and under any law
37	governing the same.
38 39	(c) Renewal application for CSP will be mailed to the address indicated on the registrant's
39 40	(c) 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
40 41	the renewal application 45 days prior to date of expiration should immediately notify DPHSS.
41 42	the renewar apprearion 45 days prior to date of expiration should infinediately noticy DPHSS.
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1 (d) No person shall engage in any activity for which registration is required until the 2 application for registration is approved and the CSR is issued by DPHSS to such person. 3 4 (e) Any person who is registered may apply to be re-registered, provided it is not more than 5 60 days from the expiration date stated on his CSR. 6 7 §41608. Filing of Application. (a) All applications shall be delivered to the Division of 8 Environmental Health of the Department of Public Health in Mangilao or mailed to the Division of 9 Environmental Health, the Department of Public Health and Social Services, P.O. Box 2816, 10 Hagatna, Guam 96932. 11 12 The post-marked date shall be considered the date of receipt by DPHSS for all (b) 13 applications received by mail. The date of acknowledged payment for application shall be 14 considered the date of receipt by DPHSS for all other applications not received by mail. 15 16 (c) Only the original, complete application with appropriate payment shall be accepted and 17 processed. Any photocopy, incomplete or illegible application, or any application not written in 18 indelible ink, or missing a required document or payment, shall not be processed and shall be 19 returned via mail. 20 21 §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 22 23 application should be granted. The failure of the applicant to provide such documents or statements 24 within ten working days after being requested to do so shall be deemed a waiver by the applicant to 25 present such documents or facts for consideration by DPHSS in granting or denying the application. 26 27 (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 U.S. Drug Enforcement 28 Administration's Controlled Substances Registration Certificate (federal registration) once that 29 30 certificate becomes available to the registrant. 31 32 §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 33 34 order to show cause pursuant to the Act. An application may be amended or withdrawn as a matter 35 of course due to a change in the applicant's federal controlled substances status or registration. 36 37 §41611. Fee Amounts. (a) For each initial Controlled Substances Registration: 38 39 (1) To manufacture controlled substances, the applicant shall pay a fee of One 40 Hundred Ninety Five Dollars (\$195) Two Hundred Twenty-Five Dollars (\$225). 41 To distribute controlled substances, the applicant shall pay a fee of One (2)Hundred Seventy Dollars (\$170) Two Hundred Dollars (\$200). 42

1 2	(3) To dispense, conduct research or instructional activities with, or to conduct chemical analysis with any controlled substance, the individual and institutional registrants
3	shall pay a fee of One Hundred-Twenty Dollars (\$120.00) One Hundred Fifty Dollars
4	(\$150), and a pharmacy shall pay a fee of One Hundred Fifty Dollars (\$150.00) One
5	Hundred Eighty Dollars (\$180).
6	
7	(b) For each renewal of Controlled Substances Registration:
8	
9	(1) To manufacture controlled substances, the registrant shall pay fee of <del>One</del>
10	Hundred Seventy Dollars (\$170) Two Hundred Dollars (\$200).
11	(2) To distribute controlled substances, the registrant shall pay fee of <del>One Hundred</del>
12	Fifty Dollars (\$150) One Hundred Eighty Dollars (\$180).
13	(3) For each renewal registration to dispense, conduct research or instructional
14	activities with, or to conduct chemical analysis with any controlled substance, the individual
15	and institutional registrants shall pay a fee of One-Hundred-Dollars (\$100.00) One Hundred
16	Thirty Dollars (\$130), and pharmacy shall pay a fee of One-Hundred Twenty Dollars
17	(\$120.00) One Hundred Fifty Dollars (\$150).
18	
19	(c) Any registrant who submits its renewal application thirty days after the expiration date
20	shall be considered a new applicant and shall pay the required initial fee.
21 22	(d) Any peristrent who has a summer CCD and is required to semicitate an undets such CCD
22 23	(d) Any registrant who has a current CSR and is required to correct or update such CSR due to shange of address or any other research requiring the reliesuones of another CSP, shall neve
23 24	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)
24 25	fee of Ten Dollars (\$10.00).
25 26	(a) Registration and re-registration face shall be paid at the time when application for
20 27	(e) Registration and re-registration fees shall be paid at the time when application for registration or re-registration is submitted for filing. Payment shall be made in the form of a
28	certified or cashiers check, money order, or personal or business check drawn through a locally
29	existing bank. Initial application and renewal application fees are non-refundable.
30	existing bank. Initial application and renewal application rees are non-relationable.
31	§41612. Persons Exempt from Fee. (a) Department of Public Health and Social Services
32	shall exempt from payment of a fee for registration or re-registration any official, employee, or
33	entity of DPHSS who or which is authorized to purchase controlled substances, to obtain such
34	substances from official stocks, to dispense such substances, to conduct research and instructional
35	activities or chemical analysis with such substances or any combination thereof in the course of his
36	or its official duties or employment.
37	or its official daties of employment.
38	(b) In order to claim exemption from payment of a registration or re-registration fee, the
39	registrant shall submit a statement wherein the registrant's supervising officer certifies to the status
40	and address of the registrant and to the authority of the registrant to acquire, possess, or otherwise
$\frac{40}{41}$	be permitted to handle controlled substances.
41 42	be permitted to manufe controlled substances.
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(c) Exemption from payment of a registration or re-registration fee does not exempt the 1 2 registrant from any other requirements or duties prescribed by law. 3 §41613. Exemption of Agents and Employees; Affiliated Practitioners. (a) The 4 5 requirement of registration is waived for any agent or employee of a person who is registered to 6 engage in any group of independent activities, if such agent or employee is acting in the usual 7 course of his business or employment. 8 9 (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 10 11 registration provided that: 12 13 (1) Such dispensing is done in the usual course of his professional practice as an employee of the institution; 14 (2) Such employed practitioner is authorized or permitted to do so by the laws of 15 16 Guam: 17 (3) The hospital or the institution has verified that the practitioner is so permitted to dispense, administer, or prescribe controlled substances in Guam; 18 (4) Such practitioner is acting only within the scope of his employment in the 19 hospital or institution: 20 (5) The hospital or the institution authorizes the practitioner to dispense under the 21 22 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 23 24 and shall be a suffix to the hospital's or institution's Guam CSR number, preceded by a hyphen (ex: H001-01 or C001-A1); and 25 26 (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 27 pharmacies registered with the Department and law enforcement agencies upon request for 28 29 the purpose of verifying the authority of the administering, dispensing, and prescribing 30 practitioner. 31 32 §41614. Exemption of Certain Military and Other Personnel. (a) The requirement of 33 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, 34 or administer, but not to procure or purchase controlled substances in the course of his official 35 36 duties. Prescriptions written by persons mentioned in this section may be honored by a pharmacy 37 outside the military installation, if so desired by the pharmacist, provided that: 38 39 (1) Pharmacist makes a reasonable effort to determine that the prescription is 40 legitimate, which may include a call back to the prescriber, and/or other good faith efforts to 41 insure the identity; and

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(2) The prescription has the branch of service/agency, service identification of

1 2	practitioner, practitioner's and patient's name and address, date, and instructions.
3	(b) If any official exempted by this section also engages as a private individual in any
4	activity or group of activities for which registration is required, such official shall obtain a
5	registration for such private activities and pay the required fee.
6	registration for buon private activities and pay are required reel
7	§41615. Exemption of Law Enforcement Officials. (a) The requirement of registration
8	is waived for the following persons in circumstances described in this section:
9	
10	(1) Any officer or employee of a Government of Guam agency who is engaged in
11	the enforcement of any Guam law relating to controlled substances and is duly authorized to
12	possess controlled substances in the course of his official duties.
13	(2) Any officer or employee of the United States Drug Enforcement
14	Administration, any officer or employee of the United States Food and Drug
15	Administration, and any other Federal officer who is lawfully engaged in the enforcement of
16	any Federal law relating to controlled substances, drugs or customs, and is duly authorized
17	to possess controlled substances in the course of his official duties, including personnel in
18	the investigative services of the military forces stationed on Guam.
19	
20	(b) Any official exempted by this section may, when acting in the course of his official
21	duties, possess a controlled substance and distribute such substance to any other official exempted
22	by this section and acting in the course of his official duties.
23	
24	(c) Any official exempted by this section may procure a controlled substance in the course
25	of an inspection, in accordance with the Act, or in the course of any criminal investigation
26	involving the person from whom the substance was procured.
27 28	(d) Low enforcement accord laboratories are not exampted from registering in order to
20 29	(d) Law enforcement agency laboratories are not exempted from registering in order to procure, obtain and transfer controlled substances for use and standards in chemical analysis.
30	Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials
31	exempted by this section and within the activity described in the Act. For purposes of this
32	paragraph, laboratory activity shall not include field or other preliminary chemical tests by officials
33	exempted by this section.
34	
35	§41616. Exemption of Civil Defense Officials. (a) The requirement of registration is
36	waived for any official of a civil defense or disaster relief organization who, in the course of his
37	official duties, is authorized to:
38	
39	(1) Maintain, and distribute for such maintenance, controlled substances held for
40	emergency use; or
41	(2) Procure controlled substances for the purpose of maintaining supplies for
42	emergency use, provided that all of such procurement is in accordance with applicable local

1 and federal laws governing controlled substances and any emergency preparedness plans of 2 Civil Defense. 3 4 (b) The requirement of registration is waived for any official of a civil defense or disaster 5 relief organization within his jurisdiction proclaimed by the Governor or by a concurrent resolution 6 of the Guam Legislature or by the Civil Defense network on Guam, which official, in the course of 7 his official duties, during such emergency or disaster, is authorized to: 8 9 (1) Dispense controlled substances; or 10 (2) Procure or distribute controlled substances, provided that all such procurement is on the official form provided by Civil Defense. 11 12 (c) Such forms may be used and are valid only during a state of emergency or disaster in 13 14 which the organization using such forms has civil defense or disaster relief jurisdiction, and which 15 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 16 17 defense emergency order forms will be deemed to be registered under the Act for purposes of 18 record keeping. 19 20 §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 21 22 application for registration and other information regarding an applicant in order to determine 23 whether the applicable standards of the Act have been met by the applicant. 24 25 §41618. Certificate of Registration. (a) DPHSS shall issue a certificate of registration to an applicant if the issuance of registration or re-registration is required under the applicable 26 27 provisions of the Act. In the event that the issuance of registration or re-registration is not appropriate, DPHSS shall deny or refuse the application. Before denying or refusing any 28 application, DPHSS shall issue an order to show cause pursuant to these rules. If requested by the 29 30 applicant, DPHSS shall hold a hearing on the application pursuant to these rules and the 31 Administrative Adjudication Law. 32 33 §41619. Suspension or Revocation of Registration. (a) DPHSS may suspend any 34 registration pursuant to the Act for any reasonable and justifiable period of time as determined by 35 DPHSS. 36 37 (b) DPHSS may revoke any registration pursuant to the Act. 38 39 (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 40 41 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. 42

1 (d) Upon service of the order of DPHSS suspending or revoking registration, the registrant 2 shall immediately surrender his certificate of registration to DPHSS. In addition, the registrant, as 3 instructed by DPHSS, shall deliver all controlled substances in his possession to DPHSS for 4 destruction. 5

6 (e) In the event that revocation or suspension is limited to a particular controlled substance 7 or substances, the registrant shall be given a new certificate of registration for all substances not 8 affected by such revocation or suspension. No fees shall be required to be paid for the new 9 certificate. The registrant shall surrender the old certificate of registration to DPHSS. In addition, 10 the registrant shall, as instructed by DPHSS, deliver to DPHSS, or to authorized agents, all of the 11 particular controlled substance or substances affected by the revocation or suspension that are in his 12 possession for destruction.

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14 §41620. Suspension of Registration Pending Final Order. (a) DPHSS may suspend any 15 registration simultaneously with or at any time subsequent to the service upon the registrant of an 16 order to show cause why such registration should not be revoked or suspended, in any case where 17 DPHSS finds that there is an imminent danger to the public health or safety. If DPHSS so 18 suspends, DPHSS shall serve with the order to show cause pursuant to the Act an order of 19 immediate suspension which shall contain the statement of DPHSS' findings regarding the danger 20 to the public health or safety.

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(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.

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**§41621.** Extension of Registration Pending Final Order. In the event that an applicant for re-registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for re-registration 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.

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1 **§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 2 determination by the applicable provisions of the Act to register the applicant, or decides to deny 3 4 the application, DPHSS shall serve upon the applicant an order to show cause why the registration 5 should not be denied. 6 7 (b) If, upon information regarding any registrant, DPHSS determines that the registration of 8 such registrant is subject to suspension or revocation pursuant to the Act, DPHSS shall serve upon 9 the registrant an order to show cause why the registration should not be revoked or suspended. 10 11 (c) The order to show cause shall call upon the registrant to appear before the DPHSS at a 12 time and place stated in the order, which shall not be less than thirty (30) calendar days after the 13 date of receipt of the order. This order to show cause shall also contain the statement of the legal 14 basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted. 15 16 17 (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 a hearing is 18 requested, DPHSS shall hold a hearing at the time and place stated in the order, pursuant to these 19 20 rules regarding hearings. 21 22 (e) When authorized by these rules and the Act, any agent of DPHSS may serve the order 23 to show cause. 24 25 (f) If the registrant or applicant does not request a hearing within the time limit as stated in 26 the Administrative Adjudication Law, then DPHSS may proceed as provided by law. 27 §41623. Hearings Generally. (a) In a case where DPHSS shall hold a hearing on any 28 29 registration or application, the procedures for such hearings shall be governed by the Administrative Adjudication Law. 30 31 32 (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. 33 34 §41624. Response to Order to Show Cause. After the filing of and service upon the 35 36 registrant of an order to show cause, the registrant has fifteen (15) calendar days after service of the 37 order in which to reply. The registrant may: 38 39 (1) Request a hearing. (2) Object to the order upon the ground that it does not state the act or omissions 40 41 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 42

1	uncertain that he cannot identify the allegations for preparative defense.		
2	(4) Admit to the accusation in whole or in part.		
3	(5) Prepare and submit new matter by way of his defense.		
4			
5	§41625. Request for Hearing. A simple request for a hearing shall be deemed a specific		
6	denial of all parts of the accusation contained within the order to show cause which are not		
7	expressly admitted. Said notice of defense shall be in writing signed by or on behalf of the		
8	applicant or registrant and shall state his mailing address and physical address, if different.		
9			
10	§41626. Filing of Response. The registrant or applicant shall file his response to the order		
11	not more than fifteen (15) calendar days after the service of the order upon him.		
12			
13	§41627. Failure to File a Notice. A failure to file a notice of defense or any notice		
14	indicating that the applicant or registrant desires a hearing and will appear upon the date stated in		
15	the order to show cause shall constitute a waiver of the applicant or registrant's right to a hearing,		
16	but DPHSS at its discretion may grant a hearing.		
17			
18	§41628. Notice. DPHSS shall include with the order to show cause served upon the		
19	applicant or registrant a notice of defense entitled as such which may be in any form satisfactory to		
20	DPHSS. Also, DPHSS shall include a notice stating that the applicant or registrant waives a		
21	hearing unless a reply is received requesting the same or stating defense or defenses to the order		
22	within the time limit as stated below of these rules. This notice shall be in substantially the form:		
23	'Unless notice, signed by or on behalf of the applicant or registrant, is delivered or mailed to the		
24	Director within fifteen (15) calendar days after receipt of the order to show cause or, at least, not		
25	less than ten (10) calendar days prior to the hearing date as stated in the order to show cause, the		
26	Director of the Department of Public Health and Social Services may proceed upon the order		
27	without a hearing. The notice of the hearing may be delivered or mailed by using the enclosed		
28	form, or any other notice of similar intent, to the Director of the Department of Public Health and		
29	Social Services, Government of Guam, Hagatna, Guam, or by personal delivery to the office of the		
30	Director, Department of Public Health and Social Services, Mangilao.'		
31			
32	§41629. Serving of Order to Show Cause. Service of the order to show cause may be		
33	made by any person so delegated by DPHSS by personally serving the applicant or registrant or by		
34	sending the order to show cause by registered mail to the last known address of the applicant or		
35	registrant as contained within his application or registration files, or by leaving a copy of the order		
36	and accompanying papers at his usual place of residence or business with some person of suitable		
37	age and discretion residing or working therein.		
38			
39	§41630. Serving of Other Materials. All other papers required to be served upon the		
40	applicant or registrant may be served in the manner of the order.		
41			
42	§41631. Amended or Supplemental Orders. At any time before the matter is submitted		
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1	for a decision, DPHSS may file or permit the filing of amended or supplemental orders. All parties
2	shall be notified if this occurs. If the amended or supplemental orders present new charges, DPHSS
3	shall afford the applicant or registrant a reasonable opportunity to prepare his defense thereto.
4	Unless DPHSS orders in the individual case, the applicant or registrant shall not be entitled to
5	further pleading. New charges shall be deemed controverted and any objections to the amended or
6	supplemental order may be made orally and shall be noted on the record.
7	
8	§41632. Time and Place of Hearing. The time and place of the hearing shall be as stated
9	on the order to show cause.
10	
11	§41633. Order to Show Cause Form. The order to show cause shall be in substantially
12	the following form, but may include any other information and the charges:
13	
14	GOVERNMENT OF GUAM
15	DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
16	IN RE THE APPLICATION OF )
17	)
18	(Applicant) under the Uniform ) ORDER TO SHOW CAUSE
19	Controlled Substances Act )
20	)
21	
22	You, (name of applicant or registrant) are hereby commanded to appear before the
23	Director of the Department of Public Health and Social Services or his delegate on day
24	of, and show cause as to why your (application or registration) under the
25	Uniform Controlled Substances Act should not be (denied, suspended, or revoked) for the following
26	reasons:
27	1. (here follows a list of the specifications and reasons for such denial, suspension or
28	revocation).
29	You may submit to the Director at the following address:
30	Director of the Department of Public Health and Social Services
31	Government of Guam
32	P.O. Box 2816
33	Hagatna, Guam 96932
34	or
35	Office of the Director
36	Department of the Public Health and Social Services
37	Mangilao, Guam
38	or their succeeding addresses
39	
40	a notice that you intend to appear before the Director or his delegate at the hearing scheduled on
41	the above date. You may also submit to the Director any objections or defenses which you might
42	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).

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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 15 testimony of any material witness residing within or without the island of Guam be taken by 16 deposition in the manner prescribed by law for depositions in civil actions. The petition shall set 17 18 forth the nature of the pending proceedings, the name and address of the witness whose testimony is 19 desired, a showing of the necessity of his testimony, a showing that the witness would be unable or 20 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 21 Guam and where the agency has ordered the taking of his testimony by deposition, the agency shall 22 23 obtain an order of court to that effect by filing a petition therefor in the District Court of Guam. 24

**§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.

- 29 30 §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 31 32 government. DPHSS may request the Attorney General of Guam to assign a member of his staff as 33 hearing officer for the case, provided that the attorney has had no prior connection with the matters 34 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 35 the admission and exclusion of evidence and advise the agency on matters of law. Where the 36 agency is holding the hearing, it shall exercise all of the powers relating to the conduct of a hearing 37 but may delegate any or all of them to the hearing officer. Where the hearing officer alone hears the 38 39 case, he shall exercise all powers relating to the conduct of the hearing.
- 40

41 **§41638.** Disqualification. A hearing officer or member of DPHSS shall voluntarily 42 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.

- 9 **§41639.** Granting of Continuance. DPHSS may grant continuances at any stage of the 10 proceeding, the need of which shall be determined by the hearing officer.
- 11

\$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.

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19 §41641. Admission of Relevant Evidence. This hearing need not be conducted according 20 to the rules relating to evidence and witnesses. Any relevant evidence shall be admitted if it is 21 evidence which responsible persons are accustomed to rely upon in the conduct of serious affairs, 22 regardless of the existence of any common law or statutory rules which might make improper the 23 admission of such evidence over objection in civil actions. Hearsay evidence may be used to 24 supplement or explain direct evidence but shall not be sufficient by and of itself to support a 25 finding, unless it would be effective to the same extent as recognized in civil actions. Irrelevant and unduly repetitive evidence may be excluded. 26 27

\$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.
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(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

1 the requirements set forth in these rules when the need for such controls decreases as a result of a 2 controlled substance being transferred to a different schedule, or a result of a controlled substance 3 being removed from control, or as a result of a significant decrease in the quantity of controlled 4 substances in the possession of the registrant during normal business operations.

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§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.

10 §41645. Security for Pharmacies. All pharmacies dispensing controlled substances in 11 Schedules II through IV 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 12 13 control station operated by the registrant. An exemption to this section may be granted by the 14 DPHSS to a pharmacy if the establishment can provide reasonable justification, in writing, for not 15 installing such system.

17 §41646. Increase in Security Requirements. In evaluating the overall security system of 18 a registrant, DPHSS may consider, but is not limited to, any of the following factors as DPHSS may 19 deem relevant to the need for stricter compliance with security requirements:

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

- 23 2. The type and form of controlled substances handled (e.g., bulk liquids or dosage units, 24 schedule, usable powders or non-usable powders); 25
  - 3. The quantity of controlled substances handled;
  - 4. The location of the premises and the relationship such location bears on security needs;
- 27 5. The type of building construction comprising the facility and the general characteristics 28 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;
- 33 10. The extent of unsupervised public access to the facility, including the presence and 34 characteristics of perimeter fencing, if any:
- 35 11. The adequacy of supervision over employees having access to manufacturing and 36 storage areas;
- 37 12. The procedures for handling business guests, visitors, maintenance personnel, and non-38 employee service personnel;
- 39 13. The availability of local police protection or of the registrant's or applicant's security 40 personnel; and
- 41 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. 42

- 1 2 §41647. Inspection: How often, Authority, and Consent. (a) DPHSS may make 3 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 4 5 sworn to before a judge of the Superior Court of Guam, pursuant to the Act. б 7 (b) An inspection, through the use of administrative warrant, shall be carried out by a 8 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 9 10 appropriate credentials, shall have the right to enter such premises and conduct inspections at 11 reasonable times and in a reasonable manner. 12 13 (c) An administrative inspection warrant shall not be required if informed consent is 14 obtained from the owner, operator, or agent in charge of the controlled premises to be inspected. 15 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 16 17 information: 18 19 1. That he (the owner, operator, or agent in charge of the premise) has been informed of his 20 constitutional right not to have an administrative inspection made without an administrative 21 inspection warrant; 22 2. That he has the right to refuse to consent to such an inspection; 23 3. That the consent given by him is voluntary and without threats of any kind; and 24 4. That he may withdraw his consent anytime during the inspection. 25 26 (d) The written consent shall be produced in duplicate with the original retained by the 27 inspector, and the duplicate to be given to the person inspected. 28 29 §41648. Prescription Information. All prescriptions for controlled substances shall 30 provide the information mandated by Federal law and any other requirements stated elsewhere in 31 these rules and the Act. 32 33 §41649. Printing and Signing of Prescription. Where an oral order is not permitted, 34 prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed 35 by the practitioner. 36 37 §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 38 examining his valid and current picture identification. Valid and current picture identification shall 39 40 be an official: 41 42
  - 1. Government of Guam Identification Card;

1	2. Passport;		
2	3. Guam Driver's license;		
3	4. Military identification card; or		
4	5. Any other legal picture identification the Director deems acceptable.		
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6	§41651. Submitting of Prescription by Third Party. In the event a prescription for		
7	controlled substance is brought to a pharmacy by an individual other than the person the		
8	prescription is written for, the pharmacist shall verify the identification of that individual before the		
9	order is filled, and the pharmacist shall print on the back of that prescription:		
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11	1. The individual's name; and		
12	2. The individual's identification number.		
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14	§41652. Acquisition of Signature. Prior to the actual dispensing of a controlled		
15	substance, a pharmacist must obtain a signature of the individual submitting a prescription for		
16	controlled substances listed in Schedules II, III, and IV. The signature shall be written on the back		
17	of the prescription.		
18			
19	§41653. Effective Date. These rules shall be effective after ninety (90) calendar days have		
20	elapsed from the dated of filing with the Legislative Secretary. At that time, all other rules and		
21	regulations or parts of other rules and regulations that conflict with these rules are repealed.		
22			
23	§41654. Separability. If any provision or application of any provision of these rules are		
24	held invalid, that invalidity shall not affect the other provisions or applications of these rules."		

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#### MINUTES OF PUBLIC HEARING Proposed Fees for the Guam Controlled Substances Registration February 16, 2010; 4:00 P.M. Division of Senior Citizens Conference Room Castle Mall, Mangilao

TOPICS	DISCUSSIONS	REMARKS AND ACTIONS TO BE TAKEN
I. Attendance	There were 2 representatives from the Department of Public Health & Social Services of the Division of Environmental Health present.	DEH Representatives Present: M. Thomas Nadeau, Administrator Cynthia Naval, Planner IV
II. Opening Remarks	Ms. Cynthia Naval, Planner IV, provided opening remarks.	<ul> <li>Hafa, Adai, My name is Cynthia Naval,</li> <li>Planner IV of the Division of Environmental</li> <li>Health of the Department of Public Health &amp;</li> <li>Social Services and present today we have</li> <li>Mr. M. Thomas Nadeau, Administrator. I</li> <li>welcome you to this public hearing on the</li> <li>existing fees for the issuance of Guam</li> <li>Controlled Substances Registration (aka</li> <li>GCSR) by the Division of Environmental</li> <li>Health. GCSR is required of all practitioners</li> <li>and institutions who manufacture, distribute,</li> <li>and/or dispense controlled substances on</li> <li>Guam. Today's public hearing is held</li> <li>pursuant to Section 3131, Division 1, Chapter</li> <li>3, of Title 5 GCA, which requires all</li> <li>Government of Guam agencies to seek public</li> <li>comments on their existing fees, pursuant to the</li> <li>Administrative Adjudication Act, or</li> <li>implement new fees for the purpose of cost</li> <li>recovery.</li> </ul> The fee schedule for the Guam Controlled Substances Registration was established through the adoption of "Rules Governing the Manufacture, Distribution and Dispensing of Controlled Substances' on November 14, 2001. Section 67.301 of Title 9 GCA, Chapter 67, otherwise known as the "Guam Uniform Controlled Substances Act", authorizes the Department of Public Health and Social Services to adopt rules and charge reasonable fees relating to the registration and control of controlled Substances. We will now formally accept any written or oral testimonies on the existing fee schedule for the Guam Controlled Substances Registrations. Dangkolo Na Si Yu'os Ma'ase!
III. Written or Oral Testimonies		No written or oral testimonies were given due to no public audience.