EDDIE BAZA CALVO
Governor

RAY TENORIO
Lieutenant Governor

Office of the Governor of Guam

December 27, 2012

31-12-2012

Office of the Speaker
Judith T. Won Pat, Ed. D.
Date 12/28/12
Time 5:04pm
Received by

2012 DEC 31 AM 11:22

Honorable Judith T. Won Pat, Ed.D.
Speaker
I Mina'trentai Unu Na Liheslaturan Guåhan
155 Hesler Street
Hagåtña, Guam 96910

Dear Madame Speaker:

Transmitted herewith is Bill No.505-31 (COR) **"AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATIONS, AND CONTROL OF THE MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED"**, which I signed into law on December 26, 2012 as **Public Law 31-272**.

Senseramente,

EDDIE BAZA CALVO

Attachment: copy of Bill

2042

I MINA'TRENTAI UNU NA LIHESLATURAN GUÅHAN
2012 (SECOND) Regular Session

CERTIFICATION OF PASSAGE OF AN ACT TO *I MAGA'LAHEN GUÅHAN*

This is to certify that **Substitute Bill No. 505-31 (COR), "AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION AND CONTROL OF THE MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED",** was on the 14th day of December, 2012, duly and regularly passed.

Benjamin J.F. Cruz
Acting Speaker

Attested:

Tina Rose Muña Barnes
Legislative Secretary

This Act was received by *I Maga'lahen Guåhan* this 17 day of Dec, 2012, at 11:40 o'clock A.M.

Rose P. Santos
Assistant Staff Officer
Maga'lahi's Office

APPROVED:

EDWARD J.B. CALVO
I Maga'lahen Guåhan

Date: DEC 26 2012

Public Law No. 31-272

MINA TRENTAI UNU NA LIHESLATURAN GUAHAN
2012 (SECOND) Regular Session

Bill No. 505-31 (COR)
As Substituted by the Committee on Health & Human Services,
Economic Development, Senior Citizens, and Election Reform.

Introduced by:

Dennis G. Rodriguez, Jr.
T. C. Ada
V. Anthony Ada
F. F. Blas, Jr.
B. J.F. Cruz
Chris M. Dueñas
Judith P. Guthertz, DPA
Sam A. Mabini, Ph.D.
T. R. Muña Barnes
Adolpho B. Palacios, Sr.
V. C. Pangelinan
R. J. Respicio
M. Silva Taijeron
Aline A. Yamashita, Ph.D.
Judith T. Won Pat, Ed.D.

AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION AND CONTROL OF THE MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent.

I Liheslaturan Guåhan finds that there is a clear public health and safety need for the implementation of the proposed administrative Rules and Regulations Governing the Guam Drug Monitoring Program of the Department of Public Health and Social Services; and further, that these rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

I Liheslaturan Guåhan finds that the proposed administrative rules and regulations as provided and required pursuant to §67.301 of Chapter 67, Title 9, Guam Code Annotated, is appropriate.

Further, *I Liheslaturan Guåhan* takes due note that the Department of Public Health and Social Services, in the development of the proposed guidelines addressed herein, promulgated the proposed rules and regulations pursuant to Article 3 - Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated. The proposed rules and regulations were reviewed by the Office of the Attorney General of Guam prior to submission to *I Liheslatura* (the Legislature) by *I Maga'låhen Guåhan,* (the Governor of Guam).

Section 2. A new Article 18 is hereby *added* to Chapter 4 of Division 1, Title 26, Guam Administrative Rules and Regulations, to read:

"ARTICLE 18. Guam Prescription Drug Monitoring Program".

Section 3. Adoption of Rules. Notwithstanding any other provision of law, rule, regulation and Executive Order, the Rules and Regulations Governing the Guam Prescription Drug Monitoring Program of the Department of Public Health and Social Services, and attached hereto as Exhibit "A", are hereby adopted by *I Mina'Trentai*

Unu Na Liheslaturan Guåhan, and *shall* be codified under Article 18 - Guam Prescription Drug Monitoring Program, of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations.

Section 4. Amendment of Rules. The Department of Public Health and Social Services *shall*, at a minimum of every five (5) years, and pursuant to Article 3-Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, the administrative rules and regulations adopted pursuant to Section 3 of this Act.

Section 5. Severability. *If* any provision of this Act or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity shall *not* affect other provisions or applications of this Act which can be given effect without the invalid provisions or application, and to this end the provisions of this Act are severable.

Section 6. Effective Date. This Act shall become immediately effective upon enactment.

Exhibit "A"

Title 26 Guam Administrative Rules and Regulations

Division 1

Chapter 4

Article 18 - Guam Prescription Drug Monitoring Program

RULES AND REGULATIONS

FOR

GUAM PRESCRIPTION DRUG MONITORING PROGRAM

Department of Public Health and Social Services

Division of Environmental Health

Guam Drug Prescription Monitoring Program

123 Chalan Kareta
Mangilao, Guam 96913-6304

EXEMPTION FROM ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules and regulations will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000) 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 and regulations.

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§ 41801. Purpose. These rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

§ 41802. Authority. These rules and regulations are adopted under the authority of § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67.

§ 41803. Title. These rules and regulations shall be known and cited as the *"Rules and Regulations Governing the Guam Prescription Drug Monitoring Program."*

§ 41804. Definitions. The definitions of terms contained in these rules and regulations are similar to those contained in Title 9 GCA, Chapter 67. If any definitions are amended in the Act, those amendments shall be the definitions of the terms contained in these rules and regulations. The following terms and phrases shall have the following meanings unless the context clearly indicates otherwise:

(a) *Abuse* means the use of a controlled substance in a manner not intended by the prescriber, which is for a therapeutic or medical use, with the intent to alter one's mood, emotion, or state of consciousness.

(b) *Board* means a professional board within the Health Professional Licensing Office of the Department that oversees health professionals who are authorized to dispense controlled substances.

(c) *Controlled substance* means a substance listed in Schedules II, III, IV, or V as defined in Title 9 GCA, Chapter 67, Article 2, as may be amended.

(d) *Controlled Substances Registration* or *CSR* means the Guam Controlled Substances Registration issued by the Department of Public Health and Social Services.

(e) *Department of Public Health and Social Services ("DPHSS")* or *Department* means the Director of the Department of Public Health and Social Services of the Government of Guam, or its successor, or any individual or entity of the department he designates.

(f) *Dispense* or *dispensing* means to deliver a controlled substance to the ultimate user, patient, or research subject by, or pursuant to, the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(g) *Dispenser* means any person who dispenses.

(h) *Diversion* means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(i) *Drug Enforcement Administration ("DEA")* means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(j) *Drug* means (i) a substance recognized as a drug in the official United States Pharmacopoeia, National Formulary, or the official Homeopathic Pharmacopoeia of the United States, or a supplement to any of them; (ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (iii) a substance, other than food, intended to affect the structure or a function of the body of individuals or animals; and (iv) a substance intended for use as a component of an article specified in subsections (i), (ii), and (iii) of this subsection. The term does not include a device or its components, parts, or accessories.

(k) *Guam Prescription Drug Monitoring Program ("GPDMP")* means the program within the Division of Environmental Health of the Department that monitors the dispensing of prescription drugs on Guam.

(l) *Guam Prescription Drug Monitoring Program Advisory Committee* or *Advisory Committee* means an advisory committee established to assist in the implementation and periodic evaluation of the Guam Prescription Drug Monitoring Program.

(m) *Guam Uniform Controlled Substances Act* or the *Act* means Title 9 Guam Code Annotated, Chapter 67.

(n) *Medicaid* means the United States health program for individuals and families with low incomes and resources, which is jointly funded by the states and federal government, and is managed by the states.

(o) *Medically Indigent Program ("MIP")* means the Guam healthcare system that provides last resort assistance to persons who do not have health insurance and who are not eligible for other healthcare coverage, such as Medicaid, Medicare, or private health insurance.

(p) *Misuse* means the use of a controlled substance in an incorrect manner.

(q) *National Drug Code ("NDC")* means a unique 10-digit, 3-segment number assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act, which identifies the labeler or vendor, product, and trade package size.

(r) *Patient* means a person who receives medical attention, care, or treatment.

(s) *Person* means an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government or governmental subdivision or agency, or any other legal or commercial entity.

(t) *Photographic Identification* means a valid and current identification that verifies a person's identity, such as a Government of Guam identification card, a passport, a Guam driver license, a military identification card, or any other legal photographic identification the Department deems acceptable.

(u) *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.

(v) *Prescribe* or *prescribing* means to give instructions, usually in writing, for the preparation and administering of a drug.

(w) *Prescriber* means a licensed, registered health care professional with authority to prescribe drugs.

(x) *Prescription* means an order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

(y) *Reasonable cause* means information or circumstances which could prompt a reasonable person to believe or suspect that there is or might be abuse or diversion of prescription drugs.

(z) *Reasonable person* means a person who exercises qualities of attention and judgment that society requires of its members for the protection of their own interest and the interests of others.

(aa)*Registrant* means any person registered pursuant to Title 9 GCA, Chapter 67.

(bb) *Ultimate User* means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household, or for administering to an animal owned by the individual or by a member of the individual's household.

§ 41805. Guam Prescription Drug Monitoring Program Advisory Committee. (a) The Department shall establish an Advisory Committee to consult with and advise the Department on matters related to the establishment, maintenance, and operation of the GPDMP; access to the GPDMP and how it is to be regulated; and security of information contained in the GPDMP database.

(b) Members of the Advisory Committee shall be determined by the Department.

§ 41806. Reporting Requirements for Dispensers. (a) Each Dispenser shall submit to the Department a report of the dispensing of all locally and federally controlled substances in Schedules II, III, IV, and V of Guam and federal law. Any dispenser located outside the boundaries of Guam and is licensed and registered by the Guam Board of Examiners for Pharmacy shall submit a report regarding each prescription dispensed to an ultimate user who resides within Guam. The information in the report shall include, at a minimum, the following:

(1) Prescriber Information:

(i) Name of prescriber;

(ii) Physical and mailing address of prescriber;

(iii) Business telephone and fax number of prescriber; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of prescriber.

(2) Patient Information:

(i) Social Security Number of patient or other government-issued identification number, e.g., passport number, driver's number;

(ii) Name of patient;

(iii) Physical and mailing address of patient;

(iv) Date of birth of patient;

(v) Gender of patient;

(vi) Name of person who received the prescription if other than the patient; and

(vii) Method of payment for the prescription.

(3) Prescription Information:

(i) Date prescription issued by prescriber;

(ii) Date prescription filled;

(iii) Prescription number;

(iv) Prescription is new or refill;

(v) Number refills ordered; and

(vi) Quantity dispensed.

(4) Controlled Substance Information or Drug Information:

(i) Prescription Drug dispensed;

(ii) National Drug Code (NDC) number for drug dispensed; and

(iii) Drug strength and quantity prescribed.

(5) Dispenser Information:

(i) Name of dispenser;

(ii) Physical and mailing address of dispenser;

(iii) Business telephone and fax number of dispenser; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of dispenser. If the dispenser reporting is a pharmacist, the DEA number and CSR number of the dispensing pharmacy may be used.

(b) Each dispenser shall submit the reported information as follows, unless a waiver is granted by the Department:

(1) Electronically;

(2) In the format required by the Department; and

(3) In the frequency and schedule determined by the Department.

§ 41807. Electronic Submission Requirement Waiver. (a) The Department may grant a waiver of the electronic submission requirement to a dispenser for good cause. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.

(b) Waivers may be granted for the following circumstances:

(1) The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will

result from being required to make electronic submissions of prescription monitoring information; or

(2) Other good cause.

(c) Requests for a waiver shall be by application in writing on a form provided by the Department for such a purpose. The dispenser requesting the waiver may provide the Department with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Department may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.

(d) Requests for a waiver shall be granted or denied by the Department no later than sixty (60) business days from the date of the written application for waiver is submitted to the Department, or the date the last supplemental written materials are received by the Department, whichever is later.

(e) The decision of the Department to grant or deny a waiver shall constitute final agency action.

§ 41808. Access to Prescription Monitoring Information by Patients. (a) A patient, or a patient's authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.

(b) A patient or a patient's authorized representative seeking access to prescription monitoring information described above shall submit a written request for information in person at the Department, or at any other place specified by the

Department. The written request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements:

(1) The patient's full name and the full name of the patient's authorized representative, if applicable;

(2) The patient's date of birth;

(3) The patient's physical and mailing address, and the complete physical and mailing address of the patient's authorized representative, if applicable;

(4) The patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and

(5) The time period for which information is being requested.

(c) The patient or the patient's authorized representative shall produce a photographic identification card prior to obtaining access to the information described above. The patient or the patient's authorized representative shall allow photocopying of the identification.

(d) Prior to obtaining access to the information described above, authorized representatives shall produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or in the case of person holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative shall allow photocopying of the documents described above. The Department may verify the patient authorization by

any reasonable means prior to providing the information to the authorized representative.

§ 41809. Access to Prescription Monitoring Information by Dispensers. (a) A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Department, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the dispenser's request.

(b) A dispenser who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If the authorization code issued by the Department is lost or compromised, the dispenser shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

§ 41810. Access to Prescription Monitoring Information by Prescribers. (a) A prescriber, or licensed health care practitioner duly authorized by a prescriber, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber's request.

(b) A prescriber, or licensed health care practitioner duly authorized by a prescriber, who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If the authorization code issued by the Department is lost or compromised, the prescriber shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.

(d) A prescriber, or licensed health care practitioner duly authorized by a prescriber, shall, before writing a prescription for a controlled substance listed in Schedule II, III, IV, or V for a patient, obtain a patient utilization report regarding the patient for the preceding twelve (12) months from the computerized program established by the Department pursuant to § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67, if the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:

(1) The patient is a new patient of the prescriber; or

(2) The patient has not received any prescription for a controlled substance from the prescriber in the preceding twelve (12) months.

The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

§ 41811. Access to Prescription Monitoring Information by the Board. (a) The Board may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Board shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Board shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41812. Access to Prescription Monitoring Information by local, state, or federal law enforcement or prosecutorial officials. (a) A local, state, or federal law enforcement or prosecutorial official may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from a local, state, or federal law enforcement or prosecutorial official shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The local, state, or federal law enforcement or prosecutorial official shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41813. Access to Prescription Monitoring Information by the authorized representatives of the Medicaid and Medically Indigent Program (MIP) within the Department of Public Health and Social Services. (a) An authorized representative of the Medicaid and Medically Indigent Program (MIP) may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department,

which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the authorized representative of the Medicaid and Medically Indigent Program (MIP) shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The authorized representative of the Medicaid and Medically Indigent Program (MIP) shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41814. Access to Prescription Monitoring Information by the Medical Examiner . (a) The Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Medical Examiner or a designee shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Medical Examiner or a designee shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41815. Access to Prescription Monitoring Information by personnel of any vendor or contractor engaged by the Department. (a) Personnel of any vendor or contractor engaged by the Department may obtain any prescription

monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.

(b) Program vendors or contractors engaged by the Department shall purge all prescription monitoring information more than six (6) years old.

§ 41816. Access to Prescription Monitoring Information by public or private entities for statistical, research, or educational purposes. A public or private entity may obtain any prescription monitoring information insofar as the information is necessary for statistical, research, or educational purposes, and insofar as information that can be used to identify a person has been removed. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

§ 41817. Designation of training programs. (a) Authorized dispensers shall attend a training course on the transmission, retrieval, and use of prescription monitoring information provided by the Department, which will be developed in consultation with the Advisory Committee, during the implementation phase of the Guam Prescription Drug Monitoring Program.

(b) Authorized prescribers who will be retrieving prescription monitoring information shall attend the training course indicated in § 41817(a) within these rules and regulations.

§ 41818. Confidentiality. Except as provided in this section, prescription monitoring information submitted to the Department shall be confidential and shall not be subject to public records laws. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in §§ 41808 to 41816 within these rules and regulations.

§ 41819. Criminal Penalties. (a) Pursuant to §§ 67.306 and 67.402(a)(3) of the Act, a dispenser who fails to submit the required information to the Department shall be guilty of a felony of the third degree.

(b) Pursuant to §§ 67.306 and 67.403(a)(4) of the Act, a dispenser who furnishes false or fraudulent information to the Department shall be guilty of a felony of the third degree.

§ 41820. Administrative Sanctions. The Department may pursue the suspension or the revocation of the registrant's CSR in accordance to § 67.304 of the Act for violating the terms of these rules and regulations, and may be subject to disciplinary action by any applicable governing entity.

§ 41821. Immunity. A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with these rules and regulations, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services.

§ 41822. Amendment of Rules and Regulations. The Department of Public Health & Social Services *shall*, at a minimum of every five years, and pursuant to Article 3- Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, these administrative rules and regulations.

§ 41823.Severability. If any provision of these rules and regulations, its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of these rules and regulations which can be given effect without the invalid provision or application, and to this end, the provisions of these rules and regulations are severable.

§ 41824.Effective Date. These rules and regulations shall be effective immediately upon enactment.

6

I MINA' TRENTAI UNU NA LIHESLATURAN GUÅHAN

2011 (SECOND) Regular Session

Date: 12/14/12

VOTING SHEET

Bill No. 505-31(COR)

Resolution No. _____

Question: _____

_____

NAME	YEAS	NAYS	NOT VOTING/ ABSTAINED	OUT DURING ROLL CALL	ABSENT
ADA, Thomas C.	✓				
ADA, V. Anthony	✓				
BLAS, Frank F., Jr.	✓				
CRUZ, Benjamin J. F.	✓				
DUENAS, Christopher M.	✓				
GUTHERTZ, Judith Paulette	✓				
MABINI, Sam					EA
MUNA-BARNES, Tina Rose	✓				
PALACIOS, Adolpho Borja, Sr.	✓				
PANGELINAN, vicente (ben) cabrera	✓				
RESPICIO, Rory J.	✓				
RODRIGUEZ, Dennis G., Jr.	✓				
SILVA TAIJERON, Mana	✓				
WON PAT, Judith T.	✓				
YAMASHITA, Aline A.	✓				
TOTAL	14	0	0	0	1

CERTIFIED TRUE AND CORRECT:

Patricia C. Santos

Clerk of the Legislature

*3 Passes = No vote

EA = Excused Absence

Ufisinan Todu Guam
SENATOR DENNIS G. RODRIGUEZ, Jr.
I Mina'trentai Unu Na Liheslaturan Guåhan
CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

2012 DEC 1 AM 11:02

December 6, 2012

Honorable Judith T. Won Pat, Ed.D.
Speaker
I Mina'Trentai Unu Na Liheslaturan Guåhan
155 Hesler Place
Hagåtña, Guam 96910

VIA: The Honorable Rory J. Respicio
Chairperson, Committee on Rules

RE: Committee Report – Bill No. 505-31(COR), as Substituted

Dear Speaker Won Pat:

Transmitted herewith, for your consideration, is the **Committee Report on Bill 505-31(COR) – An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated. Introduced by Sen. D.G. Rodriguez, Jr.,** and referred to the Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform. Bill No. 505-31(COR) was publicly heard on August 17, 2012.

Committee votes are as follows:

5 **TO PASS**
0 **NOT TO PASS**
0 **ABSTAIN**
3 **TO REPORT OUT ONLY**
0 **TO PLACE IN INACTIVE FILE**

Senseramente,

Senator Dennis G. Rodriguez, Jr.
Chairman

Attachments

176 Serenu Avenue Suite 107 Tamuning, Guam 96931
Telephone: 671.649.8638 Email: senatordrodriguez@gmail.com

Ufisinan Todu Guam
SENATOR DENNIS G. RODRIGUEZ, Jr.
I Mina'trentai Unu Na Liheslaturan Guåhan
CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

COMMITTEE REPORT
ON
Bill 505-31 (COR)
As Substituted

Introduced by Sen. Dennis G. Rodriguez Jr.

An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated.

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CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

November 26, 2012

MEMORANDUM

To: **ALL MEMBERS**
Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform.

From: **Senator Dennis G. Rodriguez, Jr.**
Committee Chairperson

Subject: **Committee Report on Bill no. 505-31(COR), as Substituted**

Transmitted herewith, for your consideration, is the **Committee Report** on **Bill 505-31(COR) – An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated. Introduced by Sen. D.G. Rodriguez, Jr.,** and referred to the Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform. This report includes the following:

- Committee Voting Sheet
- Committee Report Narrative/Digest
- Copy of Bill No. 505-31 (COR)
- Copy of Substitute Bill No. 505-31 (COR)
- Public Hearing Sign-in Sheet
- Copies of Submitted Testimony and Supporting Documents
- Copy of COR Referral of Bill No. 505-31 (COR)
- Notices of Public Hearing (1st and 2nd)
- Copy of the Public Hearing Agenda
- Related News Articles (Public hearing publication of public notice)

Please take the appropriate action on the attached voting sheet. Your attention to this matter is greatly appreciated. Should you have any questions or concerns, please do not hesitate to contact me.

Si Yu'os Ma'åse'!

Attachments

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Ufisinan Todu Guam

SENATOR DENNIS G. RODRIGUEZ, Jr.

I Mina'trentai Unu Na Liheslaturan Guåhan

CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

COMMITTEE VOTING SHEET

Substitute Bill 505-31(COR) – An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated. Introduced by Sen. D.G. Rodriguez, Jr.,

	SIGNATURE	TO PASS	NOT TO PASS	ABSTAIN	REPORT OUT ONLY	PLACE IN INACTIVE FILE
DENNIS G. RODRIGUEZ, Jr. Chairman		✓ 12/4/12				
ADOLPHO B. PALACIOS, Sr. Vice Chairman		12/5/12				
JUDITH T. WON PAT, Ed.D. Speaker						
BENJAMIN J. F. CRUZ Vice-Speaker		12/4/12				
TINA ROSE MUÑA BARNES Legislative Secretary		✓				
THOMAS C. ADA					✓ 12/6/12	
VICENTE C. PANGELINAN						
RORY J. RESPICIO						
JUDITH P. GUTHERTZ, DPA						
FRANK F. BLAS, Jr.						
V. ANTHONY ADA					✓	
ALINE A. YAMASHITA, Ph.D.						
SAM MABINI, Ph.D.						
MANA SILVA TAIJERON					12/5/12	
CHRISTOPHER M. DUENAS						

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ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

COMMITTEE REPORT DIGEST

Bill No. 505-31 (COR)

I. **OVERVIEW: The Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform conducted a public hearing on August 17, 2012.** The hearing convened at 1:06PM in I Liheslatura's Public Hearing Room. Among the items on the agenda was the consideration of **Committee Report on Bill 505-31(COR) – An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated. Introduced by Sen. D.G. Rodriguez, Jr.,** and referred to the Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform.

Public Notice Requirements
Notices were disseminated via hand-delivery/fax and/or email to all senators and all main media broadcasting outlets on August 10, 2012 (5-day notice), and again on August 13, 2012 (48-hour notice).

Senators Present

Senator Dennis G. Rodriguez, Jr.	Chairman
Senator Adolpho B. Palacios, Sr.	Vice-Chairman
Senator Thomas C. Ada	Committee Member
Senator V. Anthony Ada	Committee Member
Senator Aline A. Yamashita	Committee Member

The public hearing on agenda item Bill No. 505-31(COR) was called to order at 12:05P.M.

II. SUMMARY OF TESTIMONY & DISCUSSION.

Chairman Dennis G. Rodriguez, Jr., convened the Public Hearing on Bill 505-31(COR).
Public Notices were given:

- Friday, August 10, 2012
- Tuesday, August 14, 2012

Mr. Chairman: So far we have two people who signed up to testify, Cynthia Navel and Bill 505-31 (COR) was introduced at the request of the Governor of Guam and of course the Department of Public Health and Social Services and I understand that this has gone through the adjudication process, had a hearing and so if you could share that with us this afternoon, so now we can move forward. Cynthia?

Cynthia Navel: I am testifying on behalf of Mr. James W. Gillan. [WRITTTEN TESTIMONY]

Karen: I just wanted to say that overall of course the pharmacists are in favor of such a program being implemented here on Guam for many reasons, as already stated. However, I would appreciate a little bit of time, because I'm not sure in hearing that there was a lot of steps taken and to come this far and even I, who try to keep abreast with everything, didn't know about it until this point. I knew there was a program being started and being worked on but I didn't know that it has come along this far. I do think it would be wise to give the pharmacists, who are actually going to be affected by this, some time to at least read through it and to make any further comments on it. It is something I know that everybody out there will favor but its just a matter of giving us the opportunity to look through and to make sure it is being done in all possible ways so we don't forget something that might be vital and I do have a few things that I would like to mention at this time. As I spoke to one of them earlier, I just wanted to clarify on page 2, line 18, about what they mean about who's a dispenser. I know that its one that that followed the guidelines and I was clarified to say that it is going to be an individual as a person and we as a dispenser will mean pharmacists cause technicians wouldn't dispense controlled substances and that would be a concern on my part and going to page 7, line 18, it asks for certain information from a dispenser, such as myself, as a pharmacist, asking for name, physical and mailing address, of dispenser, business telephone and fax number, which is also okay, there's line 22 where it says professional license, so it would be my pharmacist license. We as pharmacists as not issued federal DA numbers, so I need to verify because I think that might be problem. Those are given out to prescribers and we are not prescribers were just pincers. And I know that the controlled substance registration is a local number so I don't see a problem with that. There are some states already that when you apply for a pharmacist license you also check off whether you want a controlled substance license. I'm sure there is a mechanism we can work on, my only concern is the federal level, I'd have to do more research on that and then inform all the local pharmacists what the procedures will be in terms of that and how that's going to fall. The other one on page 6, I had a concern about patient information, I know that now a days there is a lot of privacy issues and HIPPA, I don't know how comfortable patients will feel about giving out their social security numbers, I'm not sure how that goes, so that was just a point I wanted to check into, if that is legally a must, I don't know, so that was one of the things that I wanted to ask. Of course that is a very good piece of information to have because it can pin point with one number to only that individual but then again that was one of my concerns. And then on page seven line 1, name of person who receives the prescription, other than the patient, so I'm guessing it must be the person that went to the pharmacy and picked up on behalf of that patient. Right? I mean because prescription could mean the prescription itself or the prescription medication picked up. I was a little bit confused but I think if we could just word it as such, so we can just make it clear. And then on page 8 it talks about electronic requirements to be submitted on a regular basis of frequency determined by the department and I had a little bit of concern about how far along have you gone into inform the pharmacies as to what types of stuff you will need to do those things, I guess including the prescribers as well. And then it discusses about financial burden, so I'm not sure what would in tell to the local pharmacies that are going to have to implement such things and I don't know if that has been evaluated, because I know that when we went online for education of payments with private insurances, its costing a lot on the private sector, so I don't know if that is something that we need to look into. And then what type of software is going to interface with your system, so when we give it to you electronically it's going to be compatible. And then I guess setting up and educating, some of the logistics of it, I don't know, I just don't have an idea. So with all these things I just hope we can work together, as a team, to try and work together and get these things done. I do agree that the bill is a very goo bill for Guam and for many concerns for public safety. So it is a good piece of legislation.

Mr. Chairman: So Karen, you weren't informed of the hearing that they had on March 12?

Karen: I'm not sure what was the channel and I just know that I didn't get the information. I am honestly not sure, they may have emailed me, but I didn't get it.

Mr. Chairman: That's why we have these hearings, because these things come in, we usually have 90 days once it's submitted. But for things like this I always was to make sure we have the legislative hearing, so that when issues like this arise, where people were not part of the rope making process then, were able to catch it here and it seems like that didn't happen.

Karen: Yeah, I am grateful, thank goodness.

Mr. Chairman: Alright, well Senator Ada/Senator Yamashita? Any questions?

Senator Tony Ada: what rules and regulations are in use now, or have been in use since we adopted the controlled substance schedule here?

Cynthia: There are a separate set of regulations for dispensing the use of controlled substances that oversee the controlled substances program. Which is a different set of monitoring from the prescription drug monitoring program?

Karen: Correct, so there will be a new one because this is something new?

Cynthia: Yes.

Senator Ada: Okay, and is there anything in this set of rules and regulations that add additional restrictions other than those imposed by federal law?

Cynthia: No this is just strictly on reporting.

Senator Ada: Okay

Karen: Well there will be a few because like I said earlier, we have to individually get substance license for every pharmacist on island, so there is a few bit of things to do.

Cynthia: But your question about the dispenser, yes we have looked about the person and the pharm acing dispensers and in terms of the reporting in that part of the database, the pharmacy information because they would have a DEA, they would have the controlled substance registration, they would have a pharmacy number, and an AVP number.

Karen: As I mentioned line 18 says dispenser which means any person and that was my concern because or if you said any pharmacy you know.

Cynthia: Were just going beyond any pharmacy because we have that person that does dispense or physicians who dispense, who will also need to fill out this information. In the sense of a pharmacy, yes it will be the pharmacy information is what could be there in terms of dispenser.

Karen: This is just to clarify. So when I report it then I would have to have a number to report you with.

Senator Ada: So is that something that we should incorporate?

Karen: Yeah that just what I wanted to clarify because if we just stick to these rules and regs and not amend it, each pharmacist will have to apply for a CSR number or registration and as I said that shouldn't be a big issue and like I said on page 7 it says DA numbers and we as dispensers don't have those.

Cynthia: It would be an issue for the program for the reporting information to be based just on the pharmacy number. As long as your pharmacy has a separate code for each of the person who works there that dispenses your controlled substances.

Karen: then can it be worded as such, because I am reading this and I'm thinking wow do I need to get a federal number now?

Mr. Chairman: Okay so this is what we will do. So I take it your represent the Pharmacy Association? No and that's fine, and so its not as clear cut as we thought it was were still going to have to have discussions

Cynthia: I could see putting in a small section which says if the dispenser is a pharmacy then this would be the information to be required, I don't see changing this because the term goes beyond the pharmacy. So I would actually like to keep the broader length but just put a small section in there for the pharmacists.

Mr. Chairman: Okay so the Committee will work with you and also the pharmacy association and to see how we can move this quickly with those concerns.

Cynthia: And Ms. Song also had additional concerns about the costs of this, in 2010 I believe it was Melvin? We did a survey of the pharmacies on Guam that have CSRs, who dispense controlled substances medications because not every pharmacy wants to do that, and found that all 27 of them are automated. I believe that there are 4 different types of software that ware being used by them. There will not be any additional software that would need to be procured. That is also with the recording software expenses are to be recorded electronically. So with the electronic recording for this, all of the software that is going to be used by pharmacists or pharmacies on Guam is capable of reporting in the format needed electronically. It is very similar to the DEA report.

Karen: Okay, what would it be because I am not familiar because that's why I am asking.

Cynthia: There is actually a recording attrime that tells you export a DEA CD or a DEA report that's the same reporting format that we use. We worked a few months with a control programmer at attrime so that the Guam requirements were put into this and so your software was updated last year so.

Karen: So will they charge an extra fee to…

Cynthia: Oh no..

Karen: I would just like to make a suggestion, just team up with one pharmacy and try it out.

Cynthia: We actually did it with the 3 pharmacies within public health which use attribies and we did do test runs. We've already been testing the software with private pharmacies as well.

Senator Ada: Okay how would these rules affect mail to order pharmacies?

Cynthia: That is a very good question. We didn't address this for the prescription drug monitoring program on Guam, we understand that many states have got there sections with mail to order pharmacies, I believe that any off island pharmacy would be require with their own reporting. If a prescription came from Guam, it would have to state code on it and that those prescription data would be forwarded to our program. Once they are informed that we are up and running. We are very close in signing a contract with a vendor for the electronic web base reporting system. They collect data for quite a number of other states as well. So

they are a member of the off island for us based pharmacies that might do prescriptions. So anything that they do from there will be forwarded to our systems.

Karen: I do think that there should be something here that addresses that, you're telling me verbally but I don't see it here.

Mr. Chairman: I tend to agree with that also, so we could work on something like that and to put it in here to that we are able to track those mail orders as well. Okay, is there anymore of the public that wishes to testify? Sir, please state your name for the record.

Mr. Pang: My name is Patrick Pang, I'm a pharmacist here on Guam, I'm here just to concur with my colleague that there has to be further teamwork on this. Being that were so involved in this intricately, I don't feel that we were used as a source fully to gather what would be the best program possible and I think that we have a lot of input that could be valuable to include things and to exclude things. We don't need to have unnecessary reporting you know just as a payment, I'm not sure if that's an important piece of information. I'm not a computer person, so I don't know how easy that is pertaining to the reporting system and we certainly don't need to be bogged down with things like that so, but overall we want to go forward and move perfidiously to support such a program. We need to be more a part of it.

Mr. Cruz: sorry once again, Melvin Cruz, program coordinator for the program, the reason why the method of payment is there and also to all the information when we drafted this up was also based on, I did a lot of research on other legislations and a lot of it when it comes down to abuse of drugs a lot of it is cash basis also and so by keeping this data type of method that is the payment method, the system would also be able to track that because like I said when you take a look at the type of method, payment method, again if you're looking at a lot of cash out or cash payments for scheduled drugs, they may be something or some type of something going on and hopefully the system will be to. There are certain thresholds that the system has based on the type of scheduled drugs. That would be able to keep certain types of data.

Karen: I do agree with Melvin with certain types of data are vital and giving them the information that they need to track down those abusers but I also agree with my colleague, what he's trying to say here is that certain things could bog down certain daily duties of the pharmacy and he's just concerned about that part, is that how will this impact our daily routines and roles and tasks that we are already bombarded with. You know when HIPPA came out we were bombarded with consoling with private information and we train our staff all over again for HIPPA put it on file, you know that's a lot of things that are involved, I'm not saying its not good, it is good, it just that we need to make sure that we look at it and as he said we need to get the input of the people that are involved such as pharmacists. You know and see how this will play out and is that information going to be so important enough that in a negative way hinder the duties of the pharmacists at the time when were already so bombarded with so many things and other tasks. And I guess that was just a concern and he's not trying to say that it is a bad thing, and I do understand the validity of why they need such information and the helpfulness of such information.

Mr. Pang: So looking at the threshold at a point where it would trigger an alarm. This seems like there will be a lot more things before this method of payment. There seems to be very basic. We just need not to be bogged down.

Mr. Chairman: Okay I think we have enough information you know on the record now but you need to work with them and you know work with the group.

Cynthia: Actually Sir, we have these drafts were done with both the board of pharmacies and the pharmacy association. Their apart of our stakeholder group drafts of these were forwarded

to them before we had the advisory group meeting on November 17th. And that Ms. Song didn't receive her copy.

Mr. Chairman: Okay so that is behind us and we'll give you again the opportunity again to look at it and the Committee is committed to move this forward expeditiously but we want to make sure that the concerns are addressed. Okay so are there any other questions? None so the record is still open.

Hearing adjourned.

Fiscal Note: Was requested on August 14, 2012. (attached)

III. FINDINGS AND RECOMMENDATIONS

The Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform, hereby **reports out Bill No. 505-31(COR), as Substituted,** with the recommendation to Report out only.

MINA TRENTAI UNU NA LIHESLATURAN GUAHAN
2012 (SECOND) Regular Session

2012 AUG 10 AM 11:26

Bill No. 505 **-31 (COR)**

Introduced by: DENNIS G. RODRIGUEZ, Jr.

AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH& SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent.

I Liheslaturan Guåhan finds that there is a clear public health and safety need for the implementation of the proposed administrative Rules and Regulations Governing the Guam Drug Monitoring Program of the Department of Public Health & Social Services. Further, that these rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

I Liheslaturan Guahan finds that the proposed administrative rules and regulations as provided and required pursuant to §67.301 of Chapter 67, Title 9, Guam Code Annotated, is appropriate.

Further, *I Liheslaturan Guahan* takes due note that the Department of Public Health & Social Services, in the development of the proposed guidelines addressed

herein, promulgated the proposed rules and regulations pursuant to Article 3 - Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated. The proposed rules and regulations were reviewed by the Office of the Attorney General of Guam prior to submission to the Legislature by *I Maga'låhen Guåhan,* the Governor of Guam.

Section 2. A new Article 18 is hereby added to Chapter 4 of Division 1, Title 26, Guam Administrative Rules and Regulations, to read:

"ARTICLE 18. Guam Prescription Drug Monitoring Program".

Section 3. Adoption of Rules. Notwithstanding any other provision of law, rule, regulation and Executive Order, the Rules and Regulations Governing the Guam Prescription Drug Monitoring Program of the Department of Public Health & Social Services, and attached hereto as Exhibit "A", are hereby adopted by *I Mina'Trenta Na Liheslaturan Guahan,* and shall be codified under Article 18 - Guam Prescription Drug Monitoring Program, of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations.

Section 4. Amendment of Rules. The Department of Public Health & Social Services *shall*, at a minimum of every five years, and pursuant to Article 3-Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, the administrative rules and regulations adopted pursuant to Section 3 of this Act.

Section 5. Severability. *If* any provision of this Act or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity shall *not* affect other provisions or applications of this Act which can be given effect without the invalid provisions or application, and to this end the

provisions of this Act are severable.

Section 6. Effective Date. This Act shall become immediately effective upon enactment.

Exhibit "A"

Title 26 Guam Administrative Rules and Regulations

Division 1

Chapter 4

Article 18 - Guam Prescription Drug Monitoring Program

RULES AND REGULATIONS

FOR

GUAM PRESCRIPTION DRUG MONITORING PROGRAM

Department of Public Health and Social Services

Division of Environmental Health

Guam Drug Prescription Monitoring Program

123 Chalan Kareta
Mangilao, Guam 96913-6304

EXEMPTION FROM ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules and regulations will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000) 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 and regulations.

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§ 41801. Purpose. These rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

§ 41802. Authority. These rules and regulations are adopted under the authority of § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67.

§ 41803. Title. These rules and regulations shall be known and cited as the *"Rules and Regulations Governing the Guam Prescription Drug Monitoring Program."*

§ 41804. Definitions. The definitions of terms contained in these rules and regulations are similar to those contained in Title 9 GCA, Chapter 67. If any definitions are amended in the Act, those amendments shall be the definitions of the terms contained in these rules and regulations. The following terms and phrases shall have the following meanings unless the context clearly indicates otherwise:

(a) *Abuse* means the use of a controlled substance in a manner not intended by the prescriber, which is for a therapeutic or medical use, with the intent to alter one's mood, emotion, or state of consciousness.

(b) *Board* means a professional board within the Health Professional Licensing Office of the Department that oversees health professionals who are authorized to dispense controlled substances.

(c) *Controlled substance* means a substance listed in Schedules II, III, IV, or V as defined in Title 9 GCA, Chapter 67, Article 2, as may be amended.

(d) *Controlled Substances Registration* or *CSR* means the Guam Controlled Substances Registration issued by the Department of Public Health and Social Services.

(e) *Department of Public Health and Social Services ("DPHSS")* or *Department* means the Director of the Department of Public Health and Social Services of the Government of Guam, or its successor, or any individual or entity of the department he designates.

(f) *Dispense* or *dispensing* means to deliver a controlled substance to the ultimate user, patient, or research subject by, or pursuant to, the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(g) *Dispenser* means any person who dispenses.

(h) *Diversion* means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(i) *Drug Enforcement Administration ("DEA")* means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(j) *Drug* means (i) a substance recognized as a drug in the official United States Pharmacopoeia, National Formulary, or the official Homeopathic Pharmacopoeia of the United States, or a supplement to any of them; (ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (iii) a substance, other than food, intended to affect the structure or a function of the body of individuals or animals; and (iv) a substance intended for use as a component of an article specified in subsections (i), (ii), and (iii) of this section. The term does not include a device or its components, parts, or accessories.

(k) *Guam Prescription Drug Monitoring Program ("GPDMP")* means the program within the Division of Environmental Health of the Department that monitors the dispensing of prescription drugs on Guam.

(l) *Guam Prescription Drug Monitoring Program Advisory Committee* or *Advisory Committee* means an advisory committee established to assist in the implementation and periodic evaluation of the Guam Prescription Drug Monitoring Program.

(m) *Guam Uniform Controlled Substances Act* or the *Act* means Title 9 Guam Code Annotated, Chapter 67.

(n) *Medicaid* means the United States health program for individuals and families with low incomes and resources, which is jointly funded by the states and federal government, and is managed by the states.

(o) *Medically Indigent Program ("MIP")* means the Guam healthcare system that provides last resort assistance to persons who do not have health insurance and who are not eligible for other healthcare coverage, such as Medicaid, Medicare, or private health insurance.

(p) *Misuse* means the use of a controlled substance in an incorrect manner.

(q) *National Drug Code ("NDC")* means a unique 10-digit, 3-segment number assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act, which identifies the labeler or vendor, product, and trade package size.

(r) *Patient* means a person who receives medical attention, care, or treatment.

(s) *Person* means an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government or governmental subdivision or agency, or any other legal or commercial entity.

(t) *Photographic Identification* means a valid and current identification that verifies a person's identity, such as a Government of Guam identification card, a passport, a Guam driver license, a military identification card, or any other legal photographic identification the Department deems acceptable.

(u) *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.

(v) *Prescribe* or *prescribing* means to give instructions, usually in writing, for the preparation and administering of a drug.

(w) *Prescriber* means a licensed, registered health care professional with authority to prescribe drugs.

(x) *Reasonable cause* means information or circumstances which could prompt a reasonable person to believe or suspect that there is or might be abuse or diversion of prescription drugs.

(y) *Reasonable person* means a person who exercises qualities of attention and judgment that society requires of its members for the protection of their own interest and the interests of others.

(z) *Registrant* means any person registered pursuant to Title 9 GCA, Chapter 67.

(aa) *Ultimate User* means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household, or for administering to an animal owned by the individual or by a member of the individual's household.

§ 41805. Guam Prescription Drug Monitoring Program Advisory Committee. (a) The Department shall establish an Advisory Committee to consult with and advise the Department on matters related to the establishment, maintenance, and operation of the GPDMP; access to the GPDMP and how it is to be regulated; and security of information contained in the GPDMP database.

(b) Members of the Advisory Committee shall be determined by the Department.

§ 41806. Reporting Requirements for Dispensers. (a) Each Dispenser shall submit to the Department a report of the dispensing of all locally and federally controlled substances in Schedules II, III, IV, and V of Guam and federal law. The information in the report shall include, at a minimum, the following:

(1) Prescriber Information:

(i) Name of prescriber;

(ii) Physical and mailing address of prescriber;

(iii) Business telephone and fax number of prescriber; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of prescriber.

(2) Patient Information:

(i) Social Security Number of patient;

(ii) Name of patient;

(iii) Physical and mailing address of patient;

(iv) Date of birth of patient;

(v) Gender of patient;

(vi) Name of person who received the prescription if other than the patient; and

(vii) Method of payment for the prescription.

(3) Prescription Information:

(i) Date prescription issued by prescriber;

(ii) Date prescription filled;

(iii) Prescription number;

(iv) Prescription is new or refill;

(v) Number refills ordered; and

(vi) Quantity dispensed.

(4) Controlled Substance Information or Drug Information:

(i) Prescription Drug dispensed;

(ii) National Drug Code (NDC) number for drug dispensed; and

(iii) Drug strength and quantity prescribed.

(5) Dispenser Information:

(i) Name of dispenser;

(ii) Physical and mailing address of dispenser;

(iii) Business telephone and fax number of dispenser; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of dispenser.

(b) Each dispenser shall submit the reported information as follows, unless a waiver is granted by the Department:

(1) Electronically;

(2) In the format required by the Department; and

(3) In the frequency and schedule determined by the Department.

§ 41807. Electronic Submission Requirement Waiver. (a) The Department may grant a waiver of the electronic submission requirement to a dispenser for good cause. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.

(b) Waivers may be granted for the following circumstances:

(1) The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will result from being required to make electronic submissions of prescription monitoring information; or

(2) Other good cause.

(c) Requests for a waiver shall be by application in writing on a form provided by the Department for such a purpose. The dispenser requesting the waiver may provide the Department with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Department may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.

(d) Requests for a waiver shall be granted or denied by the Department no later than sixty (60) business days from the date of the written application for

waiver is submitted to the Department, or the date the last supplemental written materials are received by the Department, whichever is later.

(e) The decision of the Department to grant or deny a waiver shall constitute final agency action.

§ 41808. Access to Prescription Monitoring Information by Patients. (a) A patient, or a patient's authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.

(b) A patient or a patient's authorized representative seeking access to prescription monitoring information described above shall submit a written request for information in person at the Department, or at any other place specified by the Department. The written request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements:

(1) The patient's full name and the full name of the patient's authorized representative, if applicable;

(2) The patient's date of birth;

(3) The patient's physical and mailing address, and the complete physical and mailing address of the patient's authorized representative, if applicable;

(4) The patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and

(5) The time period for which information is being requested.

(c) The patient or the patient's authorized representative shall produce a photographic identification card prior to obtaining access to the information described above. The patient or the patient's authorized representative shall allow photocopying of the identification.

(d) Prior to obtaining access to the information described above, authorized representatives shall produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or in the case of person holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative shall allow photocopying of the documents described above. The Department may verify the patient authorization by any reasonable means prior to providing the information to the authorized representative.

§ 41809. Access to Prescription Monitoring Information by Dispensers. (a) A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Department, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the dispenser's request.

(b) A dispenser who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an

authorization code. If the authorization code issued by the Department is lost or compromised, the dispenser shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

§ 41810. Access to Prescription Monitoring Information by Prescribers. (a) A prescriber, or licensed health care practitioner duly authorized by a prescriber, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber's request.

(b) A prescriber, or licensed health care practitioner duly authorized by a prescriber, who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If

the authorization code issued by the Department is lost or compromised, the prescriber shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.

(d) A prescriber, or licensed health care practitioner duly authorized by a prescriber, shall, before writing a prescription for a controlled substance listed in Schedule II, III, IV, or V for a patient, obtain a patient utilization report regarding the patient for the preceding twelve (12) months from the computerized program established by the Department pursuant to § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67, if the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:

(1) The patient is a new patient of the prescriber; or

(2) The patient has not received any prescription for a controlled substance from the prescriber in the preceding twelve (12) months.

The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

§ 41811. Access to Prescription Monitoring Information by the Board. (a) The Board may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Board shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Board shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41812. Access to Prescription Monitoring Information by local, state, or federal law enforcement or prosecutorial officials. (a) A local, state, or federal law enforcement or prosecutorial official may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from a local, state, or federal law enforcement or prosecutorial official shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The

local, state, or federal law enforcement or prosecutorial official shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41813. Access to Prescription Monitoring Information by the authorized representatives of the Medicaid and Medically Indigent Program (MIP) within the Department of Public Health and Social Services. (a) An authorized representative of the Medicaid and Medically Indigent Program (MIP) may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the authorized representative of the Medicaid and Medically Indigent Program (MIP) shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The authorized representative of the Medicaid and Medically Indigent Program (MIP) shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41814. Access to Prescription Monitoring Information by the Medical Examiner . (a) The Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Medical Examiner or a designee shall contain identifying information regarding the registrant or patient and the time period for

which the information is being requested. The Medical Examiner or a designee shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41815. Access to Prescription Monitoring Information by personnel of any vendor or contractor engaged by the Department. (a) Personnel of any vendor or contractor engaged by the Department may obtain any prescription monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.

(b) Program vendors or contractors engaged by the Department shall purge all prescription monitoring information more than six (6) years old.

§ 41816. Access to Prescription Monitoring Information by public or private entities for statistical, research, or educational purposes. A public or private entity may obtain any prescription monitoring information insofar as the information is necessary for statistical, research, or educational purposes, and insofar as information that can be used to identify a person has been removed. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

§ 41817. Designation of training programs. (a) Authorized dispensers shall attend a training course on the transmission, retrieval, and use of prescription monitoring information provided by the Department, which will be developed in consultation with the Advisory Committee, during the implementation phase of the Guam Prescription Drug Monitoring Program.

(b) Authorized prescribers who will be retrieving prescription monitoring information shall attend the training course indicated in § 41817(a) within these rules and regulations.

§ 41818. Confidentiality. Except as provided in this section, prescription monitoring information submitted to the Department shall be confidential and shall not be subject to public records laws. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in §§ 41808 to 41816 within these rules and regulations.

§ 41819. Criminal Penalties. (a) Pursuant to §§ 67.306 and 67.402(a)(3) of the Act, a dispenser who fails to submit the required information to the Department shall be guilty of a felony of the third degree.

(b) Pursuant to §§ 67.306 and 67.403(a)(4) of the Act, a dispenser who furnishes false or fraudulent information to the Department shall be guilty of a felony of the third degree.

§ 41820. Administrative Sanctions. The Department may pursue the suspension or the revocation of the registrant's CSR in accordance to § 67.304 of the Act for violating the terms of these rules and regulations, and may be subject to disciplinary action by any applicable governing entity.

§ 41821. Immunity. A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with these rules and regulations, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services.

§ 41822. Severability. If any provision of these rules and regulations, its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of these rules and regulations which can be given effect without the invalid provision or application, and to this end, the provisions of these rules and regulations are severable.

§ 41823. Effective Date. These rules and regulations shall be effective immediately upon compliance with Title 5 GCA, Chapter 9, Article 3.

MINA TRENTAI UNU NA LIHESLATURAN GUAHAN
2012 (SECOND) Regular Session

Bill No. 505-31 (COR), as Substituted
Committee on Health & Human Services,
Economic Development, Senior Citizens, and
Election Reform.

Introduced by: DENNIS G. RODRIGUEZ, Jr.

AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH& SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent.

I Liheslaturan Guåhan finds that there is a clear public health and safety need for the implementation of the proposed administrative Rules and Regulations Governing the Guam Drug Monitoring Program of the Department of Public Health & Social Services. Further, that these rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

I Liheslaturan Guahan finds that the proposed administrative rules and regulations as provided and required pursuant to §67.301 of Chapter 67, Title 9, Guam Code Annotated, is appropriate.

Further, *I Liheslaturan Guahan* takes due note that the Department of Public Health & Social Services, in the development of the proposed guidelines addressed herein, promulgated the proposed rules and regulations pursuant to Article 3 - Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated. The proposed rules and regulations were reviewed by the Office of the Attorney General of Guam prior to submission to the Legislature by *I Maga'låhen Guåhan,* the Governor of Guam.

Section 2. A new Article 18 is hereby added to Chapter 4 of Division 1, Title 26, Guam Administrative Rules and Regulations, to read:

"ARTICLE 18. Guam Prescription Drug Monitoring Program".

Section 3. Adoption of Rules. Notwithstanding any other provision of law, rule, regulation and Executive Order, the Rules and Regulations Governing the Guam Prescription Drug Monitoring Program of the Department of Public Health & Social Services, and attached hereto as Exhibit "A", are hereby adopted by *I Mina'Trenta Na Liheslaturan Guahan,* and shall be codified under Article 18 - Guam Prescription Drug Monitoring Program, of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations.

Section 4. Amendment of Rules. The Department of Public Health & Social Services *shall*, at a minimum of every five years, and pursuant to Article 3-Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, the administrative rules and regulations adopted pursuant to Section 3 of this Act.

Section 5. Severability. *If* any provision of this Act or its application to any person or circumstance is found to be invalid or contrary to law, such

invalidity shall *not* affect other provisions or applications of this Act which can be given effect without the invalid provisions or application, and to this end the provisions of this Act are severable.

Section 6. Effective Date. This Act shall become immediately effective upon enactment.

Exhibit "A"

Title 26 Guam Administrative Rules and Regulations

Division 1

Chapter 4

Article 18 - Guam Prescription Drug Monitoring Program

RULES AND REGULATIONS

FOR

GUAM PRESCRIPTION DRUG MONITORING PROGRAM

Department of Public Health and Social Services

Division of Environmental Health

Guam Drug Prescription Monitoring Program

123 Chalan Kareta
Mangilao, Guam 96913-6304

EXEMPTION FROM ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules and regulations will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000) 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 and regulations.

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§ 41801. Purpose. These rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

§ 41802. Authority. These rules and regulations are adopted under the authority of § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67.

§ 41803. Title. These rules and regulations shall be known and cited as the *"Rules and Regulations Governing the Guam Prescription Drug Monitoring Program."*

§ 41804. Definitions. The definitions of terms contained in these rules and regulations are similar to those contained in Title 9 GCA, Chapter 67. If any definitions are amended in the Act, those amendments shall be the definitions of the terms contained in these rules and regulations. The following terms and phrases shall have the following meanings unless the context clearly indicates otherwise:

(a) *Abuse* means the use of a controlled substance in a manner not intended by the prescriber, which is for a therapeutic or medical use, with the intent to alter one's mood, emotion, or state of consciousness.

(b) *Board* means a professional board within the Health Professional Licensing Office of the Department that oversees health professionals who are authorized to dispense controlled substances.

(c) *Controlled substance* means a substance listed in Schedules II, III, IV, or V as defined in Title 9 GCA, Chapter 67, Article 2, as may be amended.

(d) *Controlled Substances Registration* or *CSR* means the Guam Controlled Substances Registration issued by the Department of Public Health and Social Services.

(e) *Department of Public Health and Social Services ("DPHSS")* or *Department* means the Director of the Department of Public Health and Social Services of the Government of Guam, or its successor, or any individual or entity of the department he designates.

(f) *Dispense* or *dispensing* means to deliver a controlled substance to the ultimate user, patient, or research subject by, or pursuant to, the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(g) *Dispenser* means any person who dispenses.

(h) *Diversion* means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(i) *Drug Enforcement Administration ("DEA")* means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(j) *Drug* means (i) a substance recognized as a drug in the official United States Pharmacopoeia, National Formulary, or the official Homeopathic Pharmacopoeia of the United States, or a supplement to any of them; (ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (iii) a substance, other than food, intended to affect the structure or a function of the body of individuals or animals; and (iv) a substance intended for use as a component of an article specified in subsections (i), (ii), and (iii) of this subsection. The term does not include a device or its components, parts, or accessories.

(k) *Guam Prescription Drug Monitoring Program ("GPDMP")* means the program within the Division of Environmental Health of the Department that monitors the dispensing of prescription drugs on Guam.

(l) *Guam Prescription Drug Monitoring Program Advisory Committee* or *Advisory Committee* means an advisory committee established to assist in the implementation and periodic evaluation of the Guam Prescription Drug Monitoring Program.

(m) *Guam Uniform Controlled Substances Act* or the *Act* means Title 9 Guam Code Annotated, Chapter 67.

(n) *Medicaid* means the United States health program for individuals and families with low incomes and resources, which is jointly funded by the states and federal government, and is managed by the states.

(o) *Medically Indigent Program ("MIP")* means the Guam healthcare system that provides last resort assistance to persons who do not have health insurance and who are not eligible for other healthcare coverage, such as Medicaid, Medicare, or private health insurance.

(p) *Misuse* means the use of a controlled substance in an incorrect manner.

(q) *National Drug Code ("NDC")* means a unique 10-digit, 3-segment number assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act, which identifies the labeler or vendor, product, and trade package size.

(r) *Patient* means a person who receives medical attention, care, or treatment.

(s) *Person* means an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government or governmental subdivision or agency, or any other legal or commercial entity.

(t) *Photographic Identification* means a valid and current identification that verifies a person's identity, such as a Government of Guam identification card, a passport, a Guam driver license, a military identification card, or any other legal photographic identification the Department deems acceptable.

(u) *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.

(v) *Prescribe* or *prescribing* means to give instructions, usually in writing, for the preparation and administering of a drug.

(w) *Prescriber* means a licensed, registered health care professional with authority to prescribe drugs.

(x) *Prescription* means an order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

(y) *Reasonable cause* means information or circumstances which could prompt a reasonable person to believe or suspect that there is or might be abuse or diversion of prescription drugs.

(z) *Reasonable person* means a person who exercises qualities of attention and judgment that society requires of its members for the protection of their own interest and the interests of others.

(aa)*Registrant* means any person registered pursuant to Title 9 GCA, Chapter 67.

(bb) *Ultimate User* means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household, or for administering to an animal owned by the individual or by a member of the individual's household.

§ 41805. Guam Prescription Drug Monitoring Program Advisory Committee. (a) The Department shall establish an Advisory Committee to consult with and advise the Department on matters related to the establishment, maintenance, and operation of the GPDMP; access to the GPDMP and how it is to be regulated; and security of information contained in the GPDMP database.

(b) Members of the Advisory Committee shall be determined by the Department.

§ 41806. Reporting Requirements for Dispensers. (a) Each Dispenser shall submit to the Department a report of the dispensing of all locally and federally controlled substances in Schedules II, III, IV, and V of Guam and federal law. Any dispenser located outside the boundaries of Guam and is licensed and registered by the Guam Board of Examiners for Pharmacy shall submit a report regarding each prescription dispensed to an ultimate user who resides within Guam. The information in the report shall include, at a minimum, the following:

(1) Prescriber Information:

(i) Name of prescriber;

(ii) Physical and mailing address of prescriber;

(iii) Business telephone and fax number of prescriber; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of prescriber.

(2) Patient Information:

(i) Social Security Number of patient or other government-issued identification number, e.g., passport number, driver's number;

(ii) Name of patient;

(iii) Physical and mailing address of patient;

(iv) Date of birth of patient;

(v) Gender of patient;

(vi) Name of person who received the prescription if other than the patient; and

(vii) Method of payment for the prescription.

(3) Prescription Information:

(i) Date prescription issued by prescriber;

(ii) Date prescription filled;

(iii) Prescription number;

(iv) Prescription is new or refill;

(v) Number refills ordered; and

(vi) Quantity dispensed.

(4) Controlled Substance Information or Drug Information:

(i) Prescription Drug dispensed;

(ii) National Drug Code (NDC) number for drug dispensed; and

(iii) Drug strength and quantity prescribed.

(5) Dispenser Information:

(i) Name of dispenser;

(ii) Physical and mailing address of dispenser;

(iii) Business telephone and fax number of dispenser; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of dispenser. If the dispenser reporting is a pharmacist, the DEA number and CSR number of the dispensing pharmacy may be used.

(b) Each dispenser shall submit the reported information as follows, unless a waiver is granted by the Department:

(1) Electronically;

(2) In the format required by the Department; and

(3) In the frequency and schedule determined by the Department.

§ 41807. Electronic Submission Requirement Waiver. (a) The Department may grant a waiver of the electronic submission requirement to a dispenser for good cause. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.

(b) Waivers may be granted for the following circumstances:

(1) The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will result from being required to make electronic submissions of prescription monitoring information; or

(2) Other good cause.

(c) Requests for a waiver shall be by application in writing on a form provided by the Department for such a purpose. The dispenser requesting the waiver may provide the Department with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Department may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.

(d) Requests for a waiver shall be granted or denied by the Department no later than sixty (60) business days from the date of the written application for waiver is submitted to the Department, or the date the last supplemental written materials are received by the Department, whichever is later.

(e) The decision of the Department to grant or deny a waiver shall constitute final agency action.

§ 41808. Access to Prescription Monitoring Information by Patients. (a) A patient, or a patient's authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.

(b) A patient or a patient's authorized representative seeking access to prescription monitoring information described above shall submit a written request for information in person at the Department, or at any other place specified by the Department. The written request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements:

(1) The patient's full name and the full name of the patient's authorized representative, if applicable;

(2) The patient's date of birth;

(3) The patient's physical and mailing address, and the complete physical and mailing address of the patient's authorized representative, if applicable;

(4) The patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and

(5) The time period for which information is being requested.

(c) The patient or the patient's authorized representative shall produce a photographic identification card prior to obtaining access to the information described above. The patient or the patient's authorized representative shall allow photocopying of the identification.

(d) Prior to obtaining access to the information described above, authorized representatives shall produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or in the case of person holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative shall allow photocopying of the documents described above. The Department may verify the patient authorization by any reasonable means prior to providing the information to the authorized representative.

§ 41809. Access to Prescription Monitoring Information by Dispensers.

(a) A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Department, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the dispenser's request.

(b) A dispenser who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If the authorization code issued by the Department is lost or compromised, the dispenser shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

§ 41810. Access to Prescription Monitoring Information by Prescribers.

(a) A prescriber, or licensed health care practitioner duly authorized by a prescriber, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber's request.

(b) A prescriber, or licensed health care practitioner duly authorized by a prescriber, who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If the authorization code issued by the Department is lost or compromised, the prescriber shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.

(d) A prescriber, or licensed health care practitioner duly authorized by a prescriber, shall, before writing a prescription for a controlled substance listed in Schedule II, III, IV, or V for a patient, obtain a patient utilization report regarding the patient for the preceding twelve (12) months from the computerized program established by the Department pursuant to § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67, if the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:

(1) The patient is a new patient of the prescriber; or

(2) The patient has not received any prescription for a controlled substance from the prescriber in the preceding twelve (12) months.

The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

§ 41811. Access to Prescription Monitoring Information by the Board. (a) The Board may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Board shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Board shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41812. Access to Prescription Monitoring Information by local, state, or federal law enforcement or prosecutorial officials. (a) A local, state, or federal law enforcement or prosecutorial official may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from a local, state, or federal law enforcement or prosecutorial official shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The local, state, or federal law enforcement or prosecutorial official shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41813. Access to Prescription Monitoring Information by the authorized representatives of the Medicaid and Medically Indigent Program (MIP) within the Department of Public Health and Social Services. (a) An authorized representative of the Medicaid and Medically Indigent Program (MIP) may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the authorized representative of the Medicaid and Medically Indigent Program (MIP) shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The authorized representative of the Medicaid and Medically Indigent

Program (MIP) shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41814. Access to Prescription Monitoring Information by the Medical Examiner . (a) The Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Medical Examiner or a designee shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Medical Examiner or a designee shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41815. Access to Prescription Monitoring Information by personnel of any vendor or contractor engaged by the Department. (a) Personnel of any vendor or contractor engaged by the Department may obtain any prescription monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.

(b) Program vendors or contractors engaged by the Department shall purge all prescription monitoring information more than six (6) years old.

§ 41816. Access to Prescription Monitoring Information by public or private entities for statistical, research, or educational purposes. A public or

private entity may obtain any prescription monitoring information insofar as the information is necessary for statistical, research, or educational purposes, and insofar as information that can be used to identify a person has been removed. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

§ 41817. Designation of training programs. (a) Authorized dispensers shall attend a training course on the transmission, retrieval, and use of prescription monitoring information provided by the Department, which will be developed in consultation with the Advisory Committee, during the implementation phase of the Guam Prescription Drug Monitoring Program.

(b) Authorized prescribers who will be retrieving prescription monitoring information shall attend the training course indicated in § 41817(a) within these rules and regulations.

§ 41818. Confidentiality. Except as provided in this section, prescription monitoring information submitted to the Department shall be confidential and shall not be subject to public records laws. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in §§ 41808 to 41816 within these rules and regulations.

§ 41819. Criminal Penalties. (a) Pursuant to §§ 67.306 and 67.402(a)(3) of the Act, a dispenser who fails to submit the required information to the Department shall be guilty of a felony of the third degree.

(b) Pursuant to §§ 67.306 and 67.403(a)(4) of the Act, a dispenser who furnishes false or fraudulent information to the Department shall be guilty of a felony of the third degree.

§ 41820. Administrative Sanctions. The Department may pursue the suspension or the revocation of the registrant's CSR in accordance to § 67.304 of the Act for violating the terms of these rules and regulations, and may be subject to disciplinary action by any applicable governing entity.

§ 41821. Immunity. A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with these rules and regulations, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services.

§ 41822. Amendment of Rules and Regulations. The Department of Public Health & Social Services *shall*, at a minimum of every five years, and pursuant to Article 3- Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, these administrative rules and regulations.

§ 41823. Severability. If any provision of these rules and regulations, its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of these rules and regulations which can be given effect without the invalid provision or application, and to this end, the provisions of these rules and regulations are severable.

§ 41824. Effective Date. These rules and regulations shall be effective immediately upon enactment.

SENATOR DENNIS G. RODRIGUEZ, Jr., Chairman

COMMITTEE ON HEALTH & HUMAN SERVICES, ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

Mina'trentai Unu Na Liheslaturan Guåhan • 31st Guam Legislature

PUBLIC HEARING DATE / TIME: Friday, August 17, 2012 12pm

- **AGENDA ITEM: Bill 505-31(COR) - An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated. Introduced by Senator Dennis G. Rodriguez, Jr.**

PRINT NAME	SIGNATURE	AGENCY or ORGANIZATION	ORAL TESTIMONY	WRITTEN TESTIMONY	IN FAVOR	OPPOSE	CONTACT NUMBERS
Karen Sang		GPhA	X		X (with comments)		488-5930
PATRICK PANG		GPhA	X		X		7875659
	More follows						

BILL NO: 505-31 (COR) Page 1 of 2

SENATOR DENNIS G. RODRIGUEZ, Jr., Chairman

COMMITTEE ON HEALTH & HUMAN SERVICES, ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

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PRINT NAME	SIGNATURE	AGENCY or ORGANIZATION	ORAL TESTIMONY	WRITTEN TESTIMONY	IN FAVOR	OPPOSE	CONTACT NUMBERS
Cynthia Naval	cynthia naval	DPHSS	X	X	X		735-7204
Melvin D. Cruz	[signature]	DPHSS	X		X		735-7563
None follows							

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

EDDIE BAZA CALVO
GOVERNOR

RAY TENORIO
LIEUTENANT GOVERNOR

JAMES W. GILLAN
DIRECTOR

LEO G. CASIL
DEPUTY DIRECTOR

Testimony in Support of Bill No. 505-31

Hafa Adai Mr. Chairman, and the members of the Committee on Health and Human Services, Senior Citizens, Economic Development, and Election Reform. I am James W. Gillan, the Director for the Department of Public Health and Social Services (DPHSS). I submit today testimony **IN SUPPORT of Bill 505-31**, an "*act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated.*"

Prescription drug monitoring programs (PDMPs) utilize a central computerized database to collect, monitor, analyze, and provide data on prescriptions for pharmaceutical controlled substances. They are tools used to protect the public health and welfare by detecting and preventing abuse and diversion of controlled substances, but at the same time not interfering with the legitimate medical need and use.

The following are goals of PDMPs:

1. **Education and Information.** PDMPs provide information and feedback to prescribers on their own prescribing trends, patient drug history, and assurance to practitioners who suspect a patient may be noncompliant in regards to prescription use.
2. **Public Health Initiatives.** Information obtained from the review and analysis of prescription monitoring data can be used in the development of public health initiatives. Such information can also be used to monitor trends and address prescribing and dispensing problems.
3. **Early Intervention and Prevention.** PDMPs can also identify patients for early assessment and treatment of prescription drug abuse, as well as deter drug diversion.

According to the Alliance of States with Prescription Monitoring Programs (ASPMP), which the Guam Prescription Drug Monitoring Program is a member of, forty-one states have operational PDMPs; eight states and Guam have enacted PDMP legislation, but the program is not yet operational; and one state has pending legislation.

The Guam Prescription Drug Monitoring Program was begun in 2008, with the first of two grants from the U.S. Department of Justice. The program's goals are to develop the regulatory foundation for the program, and to build program partnerships with providers and users of the data. One of the

necessities for the implementation of the program is to adopt the aforementioned rules and regulations.

In closing, it is our position that prescription drug monitoring programs are a good tool to protect the public's health without compromising medical care, and that the rules and regulations in Bill 505-31 provide a solid foundation for this program on Guam. *Un Dangkolo Na Si Yu'us Ma'ase!*

JAMES W. GILLAN
Director

COMMITTEE ON RULES

I Mina'trentai Unu na Liheslaturan Guåhan • The 31st Guam Legislature
155 Hesler Place, Hagåtña, Guam 96910 • *www.guamlegislature.com*
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Senator
Rory J. Respicio
CHAIRPERSON
MAJORITY LEADER

Senator
Judith P. Guthertz
VICE CHAIRPERSON
ASST. MAJORITY LEADER

MAJORITY MEMBERS:

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Vice Speaker
Benjamin J. F. Cruz

Senator
Tina Rose Muña Barnes
LEGISLATIVE SECRETARY
MAJORITY WHIP

Senator
Dennis G. Rodriguez, Jr.
ASST. MAJORITY WHIP

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Thomas C. Ada

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Senator
vicente c. pangelinan

MINORITY MEMBERS:

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Aline A. Yamashita
ASST. MINORITY LEADER

Senator
Christopher M. Duenas

Certification of Waiver of Fiscal Note Requirement

This is to certify that the Committee on Rules submitted to the Bureau of Budget and Management Research (BBMR) a request for a fiscal note, or applicable waiver, on **Bill No. 505-31 (COR) – "AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH& SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED."** – on August 10, 2012. COR hereby certifies that BBMR confirmed receipt of this request on August 10, 2012.

COR further certifies that a response to this request was not received by 5:00 P.M. on August 30, 2012, the fourteenth day after the request was received by BBMR. **Therefore, pursuant to 2 GCA §9105, the requirement for a fiscal note, or waiver thereof, on Bill 505 to be included in the committee report on said bill, is hereby waived.**

Certified by:

Rory J. Respicio

Senator Rory J. Respicio
Committee on Rules Chair

12/11/12

Date

COMMITTEE ON RULES

I Mina'trentai Unu na Liheslaturan Guåhan • The 31st Guam Legislature
155 Hesler Place, Hagåtña, Guam 96910 • *www.guamlegislature.com*
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2012 AUG 14 AM 11:26

Senator
Rory J. Respicio
CHAIRPERSON
MAJORITY LEADER

Senator
Judith P. Guthertz
VICE CHAIRPERSON
ASST. MAJORITY LEADER

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MINORITY MEMBERS:

Senator
Aline A. Yamashita
ASST. MINORITY LEADER

Senator
Christopher M. Duenas

August 14, 2012

VIA FACSIMILE
(671) 472-2825

John A. Rios
Director
Bureau of Budget & Management Research
P.O. Box 2950
Hagåtña, Guam 96910

RE: Request for Fiscal Note –
Bill Nos. 502-31 (COR) through 505-31 (COR)

Hafa Adai Mr. Rios:

Transmitted herewith is a listing of *I Mina'trentai Unu na Liheslaturan Guåhan's* most recently introduced bills. Pursuant to 2 GCA §9103, I respectfully request the preparation of fiscal notes for the referenced bills.

Si Yu'os ma'åse' for your attention to this matter.

Very Truly Yours,

Rory J. Respicio

Attachments

Cc: Clerk of the Legislature

TX Result Report

P 1
08/14/2012 11:11
Serial No. A02E011003085
TC: 193488

Destination	Start Time	Time	Prints	Result	Note
BBMR	08-14 11:10	00:00:24	002/002	OK	

Note TMR: Timer TX, POL: Polling, ORG: Original Size Setting, FHE: Frame Erase TX, MIX: Mixed Original TX, CALL: Manual TX, CSRC: CSRC, FWD: Forward, PC: PC-Fax, BND: Double-Sided Binding Direction, SP: Special Original, FCODE: F-Code, RTX: Re-TX, RLY: Relay, MBX: Confidential, BOL: Bulletin, SIP: SIP Fax, IPADR: IP Address Fax, I-FAX: Internet Fax

Result OK: Communication OK, S-OK: Stop Communication, PW-OFF: Power Switch OFF, TEL: RX from TEL, NG: Other Error, Cont: Continue, No Ans: No Answer, Refuse: Receipt Refused, Busy: Busy, M-Full:Memory Full, LOVR:Receiving length Over, POVER:Receiving page Over, FIL:File Error, DC:Decode Error, MDN:MDN Response Error, DSN:DSN Response Error.

COMMITTEE ON RULES
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ASST. MINORITY LEADER

Senator
Christopher M. Ducnas

August 14, 2012

VIA FACSIMILE
(671) 472-2825

John A. Rios
Director
Bureau of Budget & Management Research
P.O. Box 2950
Hagåtña, Guam 96910

RE: Request for Fiscal Note – Bill Nos. 502-31 (COR) through 505-31 (COR)

Hafa Adai Mr. Rios:

Transmitted herewith is a listing of *I Mina'trentai Unu na Liheslaturan Guahan's* most recently introduced bills. Pursuant to 2 GCA §9103, I respectfully request the preparation of fiscal notes for the referenced bills.

Si Yu'os ma'åse' for your attention to this matter.

Very Truly Yours,

Rory J. Respicio

Attachments

Cc: Clerk of the Legislature

Rec'd by: Annalyn
Date: 8/14/12
Time: 11:22am

COMMITTEE ON RULES

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Aline A. Yamashita
ASST. MINORITY LEADER

Senator
Christopher M. Duenas

August 10, 2012

MEMORANDUM

To: **Pat Santos**
Clerk of the Legislature

Attorney Therese M. Terlaje
Legislative Legal Counsel

From: **Senator Rory J. Respicio**
Majority Leader & Rules Chair

Subject: **Referral of Bill No. 505-31 (COR)**

As the Chairperson of the Committee on Rules, I am forwarding my referral of Bill No. 505-31 (COR).

Please ensure that the subject bill is referred, in my name, to the respective committee, as shown on the attachment. I also request that the same be forwarded to all members of *I Mina'trentai Unu na Liheslaturan Guåhan.*

Should you have any questions, please feel free to contact our office at 472-7679.

Si Yu'os Ma'åse!

(1) Attachment

I Mina'Trentai Unu Na Liheslaturan Guahan

Bill Log Sheet

BILL NOS.	SPONSOR	TITLE	DATE INTRODUCED	DATE REFERRED	120 DAY DEADLINE	CMTE REFERRED	PUBLIC HEARING DATE	DATE COMMITTEE REPORT FILED	STATUS
505-31 (COR)	D. G. Rodriguez	AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH& SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.	8/10/12 11:26am	8/10/2012		Committee on Health and Human Services, Senior Citizens,Economic Development and Election Reform			

Gmail by Google

Joseph Anthony Mesngon <jmesngon.senatordrodriguez@gmail.com>

1st Notice of Public Hearing

1 message

Clifton Herbert <cherbert.senatordrodriguez@gmail.com> Fri, Aug 10, 2012 at 4:15 PM
To: phnotice@guamlegislature.org

Ufisinan Todu Guam
SENATOR DENNIS G. RODRIGUEZ, Jr.
I Mina'trentai Unu Na Liheslaturan Guåhan
CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

Dear Senators,

Buenas yan Hafa Adai!

Please see attached first notice of public hearing.

Should you have any questions or concerns, please feel free to contact this office at anytime. Have a great weekend!

Sincerely,
Clifton Herbert
176 Serenu Avenue Suite 107 Tamuning, Guam 96931
Telephone: 671.649.8638
Email: Cherbert.senatordrodriguez@gmail.com
Website: www.toduguam.com

This e-mail may contain data that is confidential, proprietary or non-public personal information, as that term is defined in the Gramm-Leach-Bliley Act (collectively, Confidential Information).
The Confidential Information is disclosed conditioned upon your agreement that you will treat it confidentially and in accordance with applicable law, ensure that such data isn't used or disclosed except for the limited purpose for which it's being provided and will notify and cooperate with us regarding any requested or unauthorized disclosure or use of any Confidential Information.
By accepting and reviewing the Confidential information, you agree to indemnify us against any losses or expenses, including attorney's fees that we may incur as a result of any unauthorized use or disclosure of this data due to your acts or omissions. If a party other than the intended recipient receives this e-mail, he or she is requested to instantly notify us of the erroneous delivery and return to us all data so delivered.

Senators 1st Notice Public Hearing Aug. 17, 2012.pdf
80K

SENATOR DENNIS G. RODRIGUEZ, JR.

Chairman,
Committee on Health & Human Services, Senior Citizens, Economic Development, & Election Reform

Member,
Committee on Public Safety, Law Enforcement, & Judiciary

Member,
Committee on Youth, Cultural Affairs, Procurement, General Government Operations, & Public Broadcasting

Member,
Committee on Municipal Affairs, Tourism, Housing & Recreation

Member,
Committee on Rules, Federal, Foreign & Micronesian Affairs, & Human & Natural Resources

Member,
Committee on the Guam Military Buildup & Homeland Security

Member,
Committee on Appropriations, Taxation, Public Debt, Banking, Insurance, Retirement, & Land

Member,
Committee on Utilities, Transportation, Public Works, & Veterans Affairs

Assistant Majority Whip

August 10, 2012

TO: ALL SENATORS

FROM: SENATOR DENNIS G. RODRIGUEZ, JR.
CHAIRPERSON

SUBJECT: 1st NOTICE OF PUBLIC HEARING

1st NOTICE OF HEARING
Friday August 17, 2012 12:00PM

In accordance with the Open Government Law, Public Law 24-109, relative to notice for Public Meetings. Please be advised that the Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform will be conducting a hearing on August 17, 2012, at *I Liheslaturan Guåhan's* Public Hearing Room in Hagåtña, on the following:

12:00PM

- Bill No. 505-31(COR) - An act to establish the Administrative Rules and Regulations governing the Guam prescription drug monitoring program of the Department of Public Health & Social Services, under a new Article 18 of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations, and in conformance with §67.301(a) of Article 3 [Regulation of Manufacture, Distribution and Dispensing of Controlled Substances], Chapter 67, Title 9, Guam Code Annotated. *(Introduced by D. G. Rodriguez, Jr.)*

- Bill No. 499-31(COR) - An act to provide immediate financial relief to the Guam Memorial Hospital Authority by mandating timely payments by health insurance plan administrators to Guam's only civilian hospital, by adding a new §9902.1 to Article 9, Chapter 9 - [Health Care Prompt Payment Act of 2000], Title 10, Guam Code Annotated. *(Introduced by D. G. Rodriguez, Jr.)*

Ufisinan Todu Guam • 31st Guam Legislature
176 Serenu Avenue, Suite 107, Tamuning, Guam 96931 / Telephone: 671-649-TODU (8638) / Facsimile: 671-649-0520
E-mail: senatordrodriguez@gmail.com

Testimony should be addressed to Senator Dennis Rodriguez, Jr., Chairman, and may be submitted via- hand delivery to our office at 176 Serenu Avenue Suite 107 Tamuning, Guam 96931 or our mailbox at the Main Legislature Building at 155 Hesler Place, Hagåtña, Guam 96910, or via email to senatordrodriguez@gmail.com.

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For further information, please contact the Office of Senator Dennis Rodriguez, Jr. at 649-8638 (TODU)

Listserv: phnotice@guamlegislature.org

As of Oct. 25, 2012

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First notice of Public Hearing

1 message

Clifton Herbert <cherbert.senatordrodriguez@gmail.com> Fri, Aug 10, 2012 at 4:20 PM
To: clynt@spbguam.com, dcrisostomo@guampdn.com, dmgeorge@guampdn.com, dtamondong@guampdn.com, editor@mvariety.com, gdumat-ol@guampdn.com, gerry@mvguam.com, hottips@kuam.com, jason@kuam.com, john@kuam.com, jtyquiengco@spbguam.com, marvic@mvguam.com, mpieper@guampdn.com, mvariety@pticom.com, news@spbguam.com, nick.delgado@kuam.com, parroyo@k57.com, ricknauta@hitradio100.com, sabrina@kuam.com, slimtiaco@guampdn.com, therese.hart.writer@gmail.com, zita@mvguam.com, Amritha Alladi <aalladi@guampdn.com>, Arvin Temkar <aktemkar@guampdn.com>, "George, Duane M" <dmgeorge@guam.gannett.com>, gerry partido <gerrypartido.mvguam3@gmail.com>, James <officemanager@hitradio100.com>, Janela <janela@mvguam.com>, Jesse Lujan <jesselujan27@yahoo.com>, "Jon A. Anderson" <editor@mvguam.com>, Joy <joy@mvguam.com>, Jr <news@lifenews.com>, Katrina <life@guampdn.com>, Ken Quintanilla <kenq@kuam.com>, Kevin Kerrigan <kevin@spbguam.com>, Kevin Kerrigan <news@k57.com>, Laura Matthews <llmatthews@guampdn.com>, Mindy Aguon <mindy@kuam.com>, Oyaol Ngirairikl <odngirairikl@guampdn.com>, Pacific Daily News <news@guampdn.com>, "rgibson@k57.com" <rgibson@k57.com>, Travis Coffman <thebigshow@k57.com>, William Gibson <breakfastshowk57@gmail.com>
Bcc: jmesngon.senatordrodriguez@gmail.com

Ufisinan Todu Guam
SENATOR DENNIS G. RODRIGUEZ, Jr.
I Mina'trentai Unu Na Liheslaturan Guåhan
CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

Hafa Adai Newsrooms!

Please see attached notice regarding the public hearing scheduled for Friday August 17, 2012.

Should you have any questions or concerns please feel free to contact the office eat any time.

Best Regards,
Clifton Herbert

176 Serenu Avenue Suite 107 Tamuning, Guam 96931
Telephone: 671.649.8638
Email: Cherbert.senatordrodriguez@gmail.com
Website: www.toduguam.com

This e-mail may contain data that is confidential, proprietary or non-public personal information, as that term is defined in the Gramm-Leach-Bliley Act (collectively, Confidential Information).
The Confidential Information is disclosed conditioned upon your agreement that you will treat it confidentially and in accordance with applicable law, ensure that such data isn't used or disclosed except for the limited purpose for which it's being provided and will notify and cooperate with us regarding any requested or unauthorized disclosure

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2 attachments

Public Hearing 1st Notice Aug 17, 2012.pdf
370K

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547K

SENATOR DENNIS G. RODRIGUEZ, JR.

Chairman,
Committee on Health & Human Services, Senior Citizens, Economic Development, & Election Reform

Member,
Committee on Public Safety, Law Enforcement, & Judiciary

Member,
Committee on Youth, Cultural Affairs, Procurement, General Government Operations, & Public Broadcasting

Member,
Committee on Municipal Affairs, Tourism, Housing & Recreation

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Member,
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Member,
Committee on Utilities, Transportation, Public Works, & Veterans Affairs

Assistant Majority Whip

PRESS RELEASE

FIRST NOTICE OF PUBLIC HEARING

Friday, August 17, 2012 12:00PM

In accordance with the Open Government Law, Public Law 24-109, relative to notice for Public Meetings. Please be advised that the Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform will be conducting a Public Hearing **on Friday August 17, 2012 at 12:00PM.**, at *I Liheslaturan Guåhan's* Public Hearing Room in Hagåtña, on the following:

12:00PM

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For further information, please contact the Office of Senator Dennis Rodriguez, Jr. at 649-8638 (TODU)

SENATOR DENNIS G. RODRIGUEZ, JR.

Chairman,
Committee on Health & Human Services, Senior Citizens, Economic Development, & Election Reform

Member,
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Member,
Committee on Appropriations, Taxation, Public Debt, Banking, Insurance, Retirement, & Land

Member,
Committee on Utilities, Transportation, Public Works, & Veterans Affairs

Assistant Majority Whip

August 14, 2012

TO: ALL SENATORS

FROM: SENATOR DENNIS G. RODRIGUEZ, JR.
CHAIRPERSON

SUBJECT: 2nd NOTICE OF PUBLIC HEARING

2nd NOTICE OF HEARING
Friday August 17, 2012 12:00PM

In accordance with the Open Government Law, Public Law 24-109, relative to notice for Public Meetings. Please be advised that the Committee on Health & Human Services, Economic Development, Senior Citizens and Election Reform will be conducting a hearing on August 17, 2012, at *I Liheslaturan Guåhan's* Public Hearing Room in Hagåtña, on the following:

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Joseph Anthony Mesngon <jmesngon.senatordrodriguez@gmail.com>

2nd Notice of Public Hearing

2 messages

Clifton Herbert <cherbert.senatordrodriguez@gmail.com> Tue, Aug 14, 2012 at 10:16 AM
To: clynt@spbguam.com, dcrisostomo@guampdn.com, dmgeorge@guampdn.com, dtamondong@guampdn.com, editor@mvariety.com, gdumat-ol@guampdn.com, gerry@mvguam.com, hottips@kuam.com, jason@kuam.com, john@kuam.com, jtyquiengco@spbguam.com, marvic@mvguam.com, mpieper@guampdn.com, mvariety@pticom.com, news@spbguam.com, nick.delgado@kuam.com, parroyo@k57.com, ricknauta@hitradio100.com, sabrina@kuam.com, slimtiaco@guampdn.com, therese.hart.writer@gmail.com, zita@mvguam.com, Amritha Alladi <aalladi@guampdn.com>, Arvin Temkar <aktemkar@guampdn.com>, "George, Duane M" <dmgeorge@guam.gannett.com>, gerry partido <gerrypartido.mvguam3@gmail.com>, James <officemanager@hitradio100.com>, Janela <janela@mvguam.com>, Jesse Lujan <jesselujan27@yahoo.com>, "Jon A. Anderson" <editor@mvguam.com>, Joy <joy@mvguam.com>, Jr <news@lifenews.com>, Katrina <life@guampdn.com>, Ken Quintanilla <kenq@kuam.com>, Kevin Kerrigan <kevin@spbguam.com>, Kevin Kerrigan <news@k57.com>, Laura Matthews <llmatthews@guampdn.com>, Mindy Aguon <mindy@kuam.com>, Oyaol Ngirairikl <odngirairikl@guampdn.com>, Pacific Daily News <news@guampdn.com>, "rgibson@k57.com" <rgibson@k57.com>, Travis Coffman <thebigshow@k57.com>, William Gibson <breakfastshowk57@gmail.com>
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Ufisinan Todu Guam
SENATOR DENNIS G. RODRIGUEZ, Jr.
I Mina'trentai Unu Na Liheslaturan Guåhan
CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

Hafa Adai All Media!

Please see attached notice of public hearing!

Should you have any questions or concerns please feel free to contact this office at anytime.

Best Regards,
Clifton Herbert
176 Serenu Avenue Suite 107 Tamuning, Guam 96931
Telephone: 671.649.8638
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Website: www.toduguam.com

This e-mail may contain data that is confidential, proprietary or non-public personal information, as that term is defined in the Gramm-Leach-Bliley Act (collectively, Confidential Information).
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By accepting and reviewing the Confidential information, you agree to indemnify us against any losses or

expenses, including attorney's fees that we may incur as a result of any unauthorized use or disclosure of this data due to your acts or omissions. If a party other than the intended recipient receives this e-mail, he or she is requested to instantly notify us of the erroneous delivery and return to us all data so delivered.

2 attachments

Public Hearing 2nd Notice Aug 17, 2012.doc
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370K

Clifton Herbert <cherbert.senatordrodriguez@gmail.com> Tue, Aug 14, 2012 at 10:18 AM
To: phnotice@guamlegislature.org

–

Ufisinan Todu Guam
SENATOR DENNIS G. RODRIGUEZ, Jr.
I Mina'trentai Unu Na Liheslaturan Guåhan
CHAIRMAN, COMMITTEE ON HEALTH & HUMAN SERVICES,
ECONOMIC DEVELOPMENT, SENIOR CITIZENS AND ELECTION REFORM

Dear Senators,

Buenas yan Hafa Adai!

Please see attached 2nd notice of public hearing.

Should you have any questions or concerns please feel free to contact this office at any time.

Sincerely,
Clifton Herbert
[Quoted text hidden]

Senators 2nd Notice Public Hearing Aug. 17, 2012.pdf
80K

SENATOR DENNIS G. RODRIGUEZ, JR.

Chairman,
Committee on Health & Human Services, Senior Citizens, Economic Development, & Election Reform

Member,
Committee on Public Safety, Law Enforcement, & Judiciary

Member,
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Member,
Committee on Appropriations, Taxation, Public Debt, Banking, Insurance, Retirement, & Land

Member,
Committee on Utilities, Transportation, Public Works, & Veterans Affairs

Assistant Majority Whip

PRESS RELEASE

SECOND NOTICE OF PUBLIC HEARING

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Testimony should be addressed to Senator Dennis Rodriguez, Jr., Chairman, and may be submitted via- hand delivery to our office at 176 Serenu Avenue Suite 107 Tamuning, Guam 96931 or our mailbox at the Main Legislature Building at 155 Hesler Place, Hagåtña, Guam 96910, or via email to senatordrodriguez@gmail.com.

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SENATOR DENNIS G. RODRIGUEZ, JR.

Chairman,
Committee on Health & Human Services, Senior Citizens, Economic Development, & Election Reform

Member,
Committee on Public Safety, Law Enforcement, & Judiciary

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Committee on the Guam Military Buildup & Homeland Security

Member,
Committee on Appropriations, Taxation, Public Debt, Banking, Insurance, Retirement, & Land

Member,
Committee on Utilities, Transportation, Public Works, & Veterans Affairs

Assistant Majority Whip

PUBLIC HEARING AGENDA

Friday, August 17, 2012 12pm Public Hearing Room, *I Liheslatura*

I. Call to order

II. Items for public consideration:

- **Bill 499-31(COR)** - An act to provide immediate financial relief to the Guam Memorial Hospital Authority by mandating timely payments by health insurance plan administrators to Guam's only civilian hospital, by adding a new §9902.1 to Article 9, Chapter 9 - [Health Care Prompt Payment Act of 2000], Title 10, Guam Code Annotated. Introduced by Sen. Dennis G. Rodriguez, Jr.

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III. Adjournment

Thank you for your participation in today's hearing.

Ufisinan Todu Guam • 31st Guam Legislature
176 Serenu Avenue, Suite 107, Tamuning, Guam 96931 / Telephone: 671-649-TODU (8638) / Facsimile: 671-649-0520
E-mail: senatordrodriguez@gmail.com

MINA TRENTAI UNU NA LIHESLATURAN GUAHAN
2012 (SECOND) Regular Session

Bill No. 505 -31 (COR)

Introduced by: DENNIS G. RODRIGUEZ, Jr.

2012 AUG 10 AM 11:30

AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH& SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent.

I Liheslaturan Guåhan finds that there is a clear public health and safety need for the implementation of the proposed administrative Rules and Regulations Governing the Guam Drug Monitoring Program of the Department of Public Health & Social Services. Further, that these rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

I Liheslaturan Guahan finds that the proposed administrative rules and regulations as provided and required pursuant to §67.301 of Chapter 67, Title 9, Guam Code Annotated, is appropriate.

Further, *I Liheslaturan Guahan* takes due note that the Department of Public Health & Social Services, in the development of the proposed guidelines addressed

herein, promulgated the proposed rules and regulations pursuant to Article 3 - Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated. The proposed rules and regulations were reviewed by the Office of the Attorney General of Guam prior to submission to the Legislature by *I Maga'låhen Guåhan,* the Governor of Guam.

Section 2. A new Article 18 is hereby added to Chapter 4 of Division 1, Title 26, Guam Administrative Rules and Regulations, to read:

"ARTICLE 18. Guam Prescription Drug Monitoring Program".

Section 3. Adoption of Rules. Notwithstanding any other provision of law, rule, regulation and Executive Order, the Rules and Regulations Governing the Guam Prescription Drug Monitoring Program of the Department of Public Health & Social Services, and attached hereto as Exhibit "A", are hereby adopted by *I Mina'Trenta Na Liheslaturan Guahan,* and shall be codified under Article 18 - Guam Prescription Drug Monitoring Program, of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations.

Section 4. Amendment of Rules. The Department of Public Health & Social Services *shall*, at a minimum of every five years, and pursuant to Article 3- Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, the administrative rules and regulations adopted pursuant to Section 3 of this Act.

Section 5. Severability. *If* any provision of this Act or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity shall *not* affect other provisions or applications of this Act which can be given effect without the invalid provisions or application, and to this end the

provisions of this Act are severable.

Section 6. Effective Date. This Act shall become immediately effective upon enactment.

Exhibit "A"

Title 26 Guam Administrative Rules and Regulations

Division 1

Chapter 4

Article 18 - Guam Prescription Drug Monitoring Program

RULES AND REGULATIONS

FOR

GUAM PRESCRIPTION DRUG MONITORING PROGRAM

Department of Public Health and Social Services

Division of Environmental Health

Guam Drug Prescription Monitoring Program

123 Chalan Kareta
Mangilao, Guam 96913-6304

EXEMPTION FROM ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules and regulations will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000) 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 and regulations.

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§ 41801. Purpose. These rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

§ 41802. Authority. These rules and regulations are adopted under the authority of § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67.

§ 41803. Title. These rules and regulations shall be known and cited as the *"Rules and Regulations Governing the Guam Prescription Drug Monitoring Program."*

§ 41804. Definitions. The definitions of terms contained in these rules and regulations are similar to those contained in Title 9 GCA, Chapter 67. If any definitions are amended in the Act, those amendments shall be the definitions of the terms contained in these rules and regulations. The following terms and phrases shall have the following meanings unless the context clearly indicates otherwise:

(a) *Abuse* means the use of a controlled substance in a manner not intended by the prescriber, which is for a therapeutic or medical use, with the intent to alter one's mood, emotion, or state of consciousness.

(b) *Board* means a professional board within the Health Professional Licensing Office of the Department that oversees health professionals who are authorized to dispense controlled substances.

(c) *Controlled substance* means a substance listed in Schedules II, III, IV, or V as defined in Title 9 GCA, Chapter 67, Article 2, as may be amended.

(d) *Controlled Substances Registration* or *CSR* means the Guam Controlled Substances Registration issued by the Department of Public Health and Social Services.

(e) *Department of Public Health and Social Services ("DPHSS")* or *Department* means the Director of the Department of Public Health and Social Services of the Government of Guam, or its successor, or any individual or entity of the department he designates.

(f) *Dispense* or *dispensing* means to deliver a controlled substance to the ultimate user, patient, or research subject by, or pursuant to, the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(g) *Dispenser* means any person who dispenses.

(h) *Diversion* means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(i) *Drug Enforcement Administration ("DEA")* means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(j) *Drug* means (i) a substance recognized as a drug in the official United States Pharmacopoeia, National Formulary, or the official Homeopathic Pharmacopoeia of the United States, or a supplement to any of them; (ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (iii) a substance, other than food, intended to affect the structure or a function of the body of individuals or animals; and (iv) a substance intended for use as a component of an article specified in subsections (i), (ii), and (iii) of this section. The term does not include a device or its components, parts, or accessories.

(k) *Guam Prescription Drug Monitoring Program ("GPDMP")* means the program within the Division of Environmental Health of the Department that monitors the dispensing of prescription drugs on Guam.

(l) *Guam Prescription Drug Monitoring Program Advisory Committee* or *Advisory Committee* means an advisory committee established to assist in the implementation and periodic evaluation of the Guam Prescription Drug Monitoring Program.

(m) *Guam Uniform Controlled Substances Act* or the *Act* means Title 9 Guam Code Annotated, Chapter 67.

(n) *Medicaid* means the United States health program for individuals and families with low incomes and resources, which is jointly funded by the states and federal government, and is managed by the states.

(o) *Medically Indigent Program ("MIP")* means the Guam healthcare system that provides last resort assistance to persons who do not have health insurance and who are not eligible for other healthcare coverage, such as Medicaid, Medicare, or private health insurance.

(p) *Misuse* means the use of a controlled substance in an incorrect manner.

(q) *National Drug Code ("NDC")* means a unique 10-digit, 3-segment number assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act, which identifies the labeler or vendor, product, and trade package size.

(r) *Patient* means a person who receives medical attention, care, or treatment.

(s) *Person* means an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government or governmental subdivision or agency, or any other legal or commercial entity.

(t) *Photographic Identification* means a valid and current identification that verifies a person's identity, such as a Government of Guam identification card, a passport, a Guam driver license, a military identification card, or any other legal photographic identification the Department deems acceptable.

(u) *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.

(v) *Prescribe* or *prescribing* means to give instructions, usually in writing, for the preparation and administering of a drug.

(w) *Prescriber* means a licensed, registered health care professional with authority to prescribe drugs.

(x) *Reasonable cause* means information or circumstances which could prompt a reasonable person to believe or suspect that there is or might be abuse or diversion of prescription drugs.

(y) *Reasonable person* means a person who exercises qualities of attention and judgment that society requires of its members for the protection of their own interest and the interests of others.

(z) *Registrant* means any person registered pursuant to Title 9 GCA, Chapter 67.

(aa) *Ultimate User* means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household, or for administering to an animal owned by the individual or by a member of the individual's household.

§ 41805. Guam Prescription Drug Monitoring Program Advisory Committee. (a) The Department shall establish an Advisory Committee to consult with and advise the Department on matters related to the establishment, maintenance, and operation of the GPDMP; access to the GPDMP and how it is to be regulated; and security of information contained in the GPDMP database.

(b) Members of the Advisory Committee shall be determined by the Department.

§ 41806. Reporting Requirements for Dispensers. (a) Each Dispenser shall submit to the Department a report of the dispensing of all locally and federally controlled substances in Schedules II, III, IV, and V of Guam and federal law. The information in the report shall include, at a minimum, the following:

(1) Prescriber Information:

(i) Name of prescriber;

(ii) Physical and mailing address of prescriber;

(iii) Business telephone and fax number of prescriber; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of prescriber.

(2) Patient Information:

(i) Social Security Number of patient;

(ii) Name of patient;

(iii) Physical and mailing address of patient;

(iv) Date of birth of patient;

(v) Gender of patient;

(vi) Name of person who received the prescription if other than the patient; and

(vii) Method of payment for the prescription.

(3) Prescription Information:

(i) Date prescription issued by prescriber;

(ii) Date prescription filled;

(iii) Prescription number;

(iv) Prescription is new or refill;

(v) Number refills ordered; and

(vi) Quantity dispensed.

(4) Controlled Substance Information or Drug Information:

(i) Prescription Drug dispensed;

(ii) National Drug Code (NDC) number for drug dispensed; and

(iii) Drug strength and quantity prescribed.

(5) Dispenser Information:

(i) Name of dispenser;

(ii) Physical and mailing address of dispenser;

(iii) Business telephone and fax number of dispenser; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of dispenser.

(b) Each dispenser shall submit the reported information as follows, unless a waiver is granted by the Department:

(1) Electronically;

(2) In the format required by the Department; and

(3) In the frequency and schedule determined by the Department.

§ 41807. Electronic Submission Requirement Waiver. (a) The Department may grant a waiver of the electronic submission requirement to a dispenser for good cause. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.

(b) Waivers may be granted for the following circumstances:

(1) The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will result from being required to make electronic submissions of prescription monitoring information; or

(2) Other good cause.

(c) Requests for a waiver shall be by application in writing on a form provided by the Department for such a purpose. The dispenser requesting the waiver may provide the Department with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Department may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.

(d) Requests for a waiver shall be granted or denied by the Department no later than sixty (60) business days from the date of the written application for

waiver is submitted to the Department, or the date the last supplemental written materials are received by the Department, whichever is later.

(e) The decision of the Department to grant or deny a waiver shall constitute final agency action.

§ 41808. Access to Prescription Monitoring Information by Patients. (a) A patient, or a patient's authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.

(b) A patient or a patient's authorized representative seeking access to prescription monitoring information described above shall submit a written request for information in person at the Department, or at any other place specified by the Department. The written request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements:

(1) The patient's full name and the full name of the patient's authorized representative, if applicable;

(2) The patient's date of birth;

(3) The patient's physical and mailing address, and the complete physical and mailing address of the patient's authorized representative, if applicable;

(4) The patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and

(5) The time period for which information is being requested.

(c) The patient or the patient's authorized representative shall produce a photographic identification card prior to obtaining access to the information described above. The patient or the patient's authorized representative shall allow photocopying of the identification.

(d) Prior to obtaining access to the information described above, authorized representatives shall produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or in the case of person holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative shall allow photocopying of the documents described above. The Department may verify the patient authorization by any reasonable means prior to providing the information to the authorized representative.

§ 41809. Access to Prescription Monitoring Information by Dispensers. (a) A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Department, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the dispenser's request.

(b) A dispenser who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an

authorization code. If the authorization code issued by the Department is lost or compromised, the dispenser shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

§ 41810. Access to Prescription Monitoring Information by Prescribers.

(a) A prescriber, or licensed health care practitioner duly authorized by a prescriber, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber's request.

(b) A prescriber, or licensed health care practitioner duly authorized by a prescriber, who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If

the authorization code issued by the Department is lost or compromised, the prescriber shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.

(d) A prescriber, or licensed health care practitioner duly authorized by a prescriber, shall, before writing a prescription for a controlled substance listed in Schedule II, III, IV, or V for a patient, obtain a patient utilization report regarding the patient for the preceding twelve (12) months from the computerized program established by the Department pursuant to § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67, if the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:

(1) The patient is a new patient of the prescriber; or

(2) The patient has not received any prescription for a controlled substance from the prescriber in the preceding twelve (12) months.

The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

§ 41811. Access to Prescription Monitoring Information by the Board. (a) The Board may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Board shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Board shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41812. Access to Prescription Monitoring Information by local, state, or federal law enforcement or prosecutorial officials. (a) A local, state, or federal law enforcement or prosecutorial official may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from a local, state, or federal law enforcement or prosecutorial official shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The

local, state, or federal law enforcement or prosecutorial official shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41813. Access to Prescription Monitoring Information by the authorized representatives of the Medicaid and Medically Indigent Program (MIP) within the Department of Public Health and Social Services. (a) An authorized representative of the Medicaid and Medically Indigent Program (MIP) may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the authorized representative of the Medicaid and Medically Indigent Program (MIP) shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The authorized representative of the Medicaid and Medically Indigent Program (MIP) shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41814. Access to Prescription Monitoring Information by the Medical Examiner . (a) The Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Medical Examiner or a designee shall contain identifying information regarding the registrant or patient and the time period for

which the information is being requested. The Medical Examiner or a designee shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41815. Access to Prescription Monitoring Information by personnel of any vendor or contractor engaged by the Department. (a) Personnel of any vendor or contractor engaged by the Department may obtain any prescription monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.

(b) Program vendors or contractors engaged by the Department shall purge all prescription monitoring information more than six (6) years old.

§ 41816. Access to Prescription Monitoring Information by public or private entities for statistical, research, or educational purposes. A public or private entity may obtain any prescription monitoring information insofar as the information is necessary for statistical, research, or educational purposes, and insofar as information that can be used to identify a person has been removed. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

§ 41817. Designation of training programs. (a) Authorized dispensers shall attend a training course on the transmission, retrieval, and use of prescription monitoring information provided by the Department, which will be developed in consultation with the Advisory Committee, during the implementation phase of the Guam Prescription Drug Monitoring Program.

(b) Authorized prescribers who will be retrieving prescription monitoring information shall attend the training course indicated in § 41817(a) within these rules and regulations.

§ 41818. Confidentiality. Except as provided in this section, prescription monitoring information submitted to the Department shall be confidential and shall not be subject to public records laws. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in §§ 41808 to 41816 within these rules and regulations.

§ 41819. Criminal Penalties. (a) Pursuant to §§ 67.306 and 67.402(a)(3) of the Act, a dispenser who fails to submit the required information to the Department shall be guilty of a felony of the third degree.

(b) Pursuant to §§ 67.306 and 67.403(a)(4) of the Act, a dispenser who furnishes false or fraudulent information to the Department shall be guilty of a felony of the third degree.

§ 41820. Administrative Sanctions. The Department may pursue the suspension or the revocation of the registrant's CSR in accordance to § 67.304 of the Act for violating the terms of these rules and regulations, and may be subject to disciplinary action by any applicable governing entity.

§ 41821. Immunity. A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with these rules and regulations, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services.

§ 41822. Severability. If any provision of these rules and regulations, its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of these rules and regulations which can be given effect without the invalid provision or application, and to this end, the provisions of these rules and regulations are severable.

§ 41823. Effective Date. These rules and regulations shall be effective immediately upon compliance with Title 5 GCA, Chapter 9, Article 3.

MINA TRENTAI UNU NA LIHESLATURAN GUAHAN
2012 (SECOND) Regular Session

Bill No. 505 -31 (COR)

Introduced by: DENNIS G. RODRIGUEZ, Jr.

2012 AUG 10 AM 11:30

AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH& SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent.

I Liheslaturan Guåhan finds that there is a clear public health and safety need for the implementation of the proposed administrative Rules and Regulations Governing the Guam Drug Monitoring Program of the Department of Public Health & Social Services. Further, that these rules and regulations implement the monitoring of pharmaceutical controlled substances through the establishment of an electronic database and reporting system to prevent the misuse, abuse, and diversion of such drugs without interfering with its legal medical use.

I Liheslaturan Guahan finds that the proposed administrative rules and regulations as provided and required pursuant to §67.301 of Chapter 67, Title 9, Guam Code Annotated, is appropriate.

Further, *I Liheslaturan Guahan* takes due note that the Department of Public Health & Social Services, in the development of the proposed guidelines addressed

herein, promulgated the proposed rules and regulations pursuant to Article 3 - Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated. The proposed rules and regulations were reviewed by the Office of the Attorney General of Guam prior to submission to the Legislature by *I Maga'låhen Guåhan,* the Governor of Guam.

Section 2. A new Article 18 is hereby added to Chapter 4 of Division 1, Title 26, Guam Administrative Rules and Regulations, to read:

"ARTICLE 18. Guam Prescription Drug Monitoring Program".

Section 3. Adoption of Rules. Notwithstanding any other provision of law, rule, regulation and Executive Order, the Rules and Regulations Governing the Guam Prescription Drug Monitoring Program of the Department of Public Health & Social Services, and attached hereto as Exhibit "A", are hereby adopted by *I Mina'Trenta Na Liheslaturan Guahan,* and shall be codified under Article 18 - Guam Prescription Drug Monitoring Program, of Chapter 4, Division 1, Title 26, Guam Administrative Rules and Regulations.

Section 4. Amendment of Rules. The Department of Public Health & Social Services *shall*, at a minimum of every five years, and pursuant to Article 3- Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and amend, as may be necessary, the administrative rules and regulations adopted pursuant to Section 3 of this Act.

Section 5. Severability. *If* any provision of this Act or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity shall *not* affect other provisions or applications of this Act which can be given effect without the invalid provisions or application, and to this end the

provisions of this Act are severable.

Section 6. Effective Date. This Act shall become immediately effective upon enactment.

Exhibit "A"

Title 26 Guam Administrative Rules and Regulations

Division 1

Chapter 4

Article 18 - Guam Prescription Drug Monitoring Program

RULES AND REGULATIONS

FOR

GUAM PRESCRIPTION DRUG MONITORING PROGRAM

Department of Public Health and Social Services

Division of Environmental Health

Guam Drug Prescription Monitoring Program

123 Chalan Kareta
Mangilao, Guam 96913-6304

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The implementation of the following proposed rules and regulations will not have an economic impact to the public of more than Five Hundred Thousand Dollars ($500,000) 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 and regulations.

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(a) *Abuse* means the use of a controlled substance in a manner not intended by the prescriber, which is for a therapeutic or medical use, with the intent to alter one's mood, emotion, or state of consciousness.

(b) *Board* means a professional board within the Health Professional Licensing Office of the Department that oversees health professionals who are authorized to dispense controlled substances.

(c) *Controlled substance* means a substance listed in Schedules II, III, IV, or V as defined in Title 9 GCA, Chapter 67, Article 2, as may be amended.

(d) *Controlled Substances Registration* or *CSR* means the Guam Controlled Substances Registration issued by the Department of Public Health and Social Services.

(e) *Department of Public Health and Social Services ("DPHSS")* or *Department* means the Director of the Department of Public Health and Social Services of the Government of Guam, or its successor, or any individual or entity of the department he designates.

(f) *Dispense* or *dispensing* means to deliver a controlled substance to the ultimate user, patient, or research subject by, or pursuant to, the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(g) *Dispenser* means any person who dispenses.

(h) *Diversion* means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

(i) *Drug Enforcement Administration ("DEA")* means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(j) *Drug* means (i) a substance recognized as a drug in the official United States Pharmacopoeia, National Formulary, or the official Homeopathic Pharmacopoeia of the United States, or a supplement to any of them; (ii) a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (iii) a substance, other than food, intended to affect the structure or a function of the body of individuals or animals; and (iv) a substance intended for use as a component of an article specified in subsections (i), (ii), and (iii) of this section. The term does not include a device or its components, parts, or accessories.

(k) *Guam Prescription Drug Monitoring Program ("GPDMP")* means the program within the Division of Environmental Health of the Department that monitors the dispensing of prescription drugs on Guam.

(l) *Guam Prescription Drug Monitoring Program Advisory Committee* or *Advisory Committee* means an advisory committee established to assist in the implementation and periodic evaluation of the Guam Prescription Drug Monitoring Program.

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(n) *Medicaid* means the United States health program for individuals and families with low incomes and resources, which is jointly funded by the states and federal government, and is managed by the states.

(o) *Medically Indigent Program ("MIP")* means the Guam healthcare system that provides last resort assistance to persons who do not have health insurance and who are not eligible for other healthcare coverage, such as Medicaid, Medicare, or private health insurance.

(p) *Misuse* means the use of a controlled substance in an incorrect manner.

(q) *National Drug Code ("NDC")* means a unique 10-digit, 3-segment number assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act, which identifies the labeler or vendor, product, and trade package size.

(r) *Patient* means a person who receives medical attention, care, or treatment.

(s) *Person* means an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government or governmental subdivision or agency, or any other legal or commercial entity.

(t) *Photographic Identification* means a valid and current identification that verifies a person's identity, such as a Government of Guam identification card, a passport, a Guam driver license, a military identification card, or any other legal photographic identification the Department deems acceptable.

(u) *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.

(v) *Prescribe* or *prescribing* means to give instructions, usually in writing, for the preparation and administering of a drug.

(w) *Prescriber* means a licensed, registered health care professional with authority to prescribe drugs.

(x) *Reasonable cause* means information or circumstances which could prompt a reasonable person to believe or suspect that there is or might be abuse or diversion of prescription drugs.

(y) *Reasonable person* means a person who exercises qualities of attention and judgment that society requires of its members for the protection of their own interest and the interests of others.

(z) *Registrant* means any person registered pursuant to Title 9 GCA, Chapter 67.

(aa) *Ultimate User* means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household, or for administering to an animal owned by the individual or by a member of the individual's household.

§ 41805. Guam Prescription Drug Monitoring Program Advisory Committee. (a) The Department shall establish an Advisory Committee to consult with and advise the Department on matters related to the establishment, maintenance, and operation of the GPDMP; access to the GPDMP and how it is to be regulated; and security of information contained in the GPDMP database.

(b) Members of the Advisory Committee shall be determined by the Department.

§ 41806. Reporting Requirements for Dispensers. (a) Each Dispenser shall submit to the Department a report of the dispensing of all locally and federally controlled substances in Schedules II, III, IV, and V of Guam and federal law. The information in the report shall include, at a minimum, the following:

(1) Prescriber Information:

(i) Name of prescriber;

(ii) Physical and mailing address of prescriber;

(iii) Business telephone and fax number of prescriber; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of prescriber.

(2) Patient Information:

(i) Social Security Number of patient;

(ii) Name of patient;

(iii) Physical and mailing address of patient;

(iv) Date of birth of patient;

(v) Gender of patient;

(vi) Name of person who received the prescription if other than the patient; and

(vii) Method of payment for the prescription.

(3) Prescription Information:

(i) Date prescription issued by prescriber;

(ii) Date prescription filled;

(iii) Prescription number;

(iv) Prescription is new or refill;

(v) Number refills ordered; and

(vi) Quantity dispensed.

(4) Controlled Substance Information or Drug Information:

(i) Prescription Drug dispensed;

(ii) National Drug Code (NDC) number for drug dispensed; and

(iii) Drug strength and quantity prescribed.

(5) Dispenser Information:

(i) Name of dispenser;

(ii) Physical and mailing address of dispenser;

(iii) Business telephone and fax number of dispenser; and

(iv) Professional license, DEA registration number and Controlled Substances Registration (CSR) of dispenser.

(b) Each dispenser shall submit the reported information as follows, unless a waiver is granted by the Department:

(1) Electronically;

(2) In the format required by the Department; and

(3) In the frequency and schedule determined by the Department.

§ 41807. Electronic Submission Requirement Waiver. (a) The Department may grant a waiver of the electronic submission requirement to a dispenser for good cause. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.

(b) Waivers may be granted for the following circumstances:

(1) The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will result from being required to make electronic submissions of prescription monitoring information; or

(2) Other good cause.

(c) Requests for a waiver shall be by application in writing on a form provided by the Department for such a purpose. The dispenser requesting the waiver may provide the Department with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Department may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.

(d) Requests for a waiver shall be granted or denied by the Department no later than sixty (60) business days from the date of the written application for

waiver is submitted to the Department, or the date the last supplemental written materials are received by the Department, whichever is later.

(e) The decision of the Department to grant or deny a waiver shall constitute final agency action.

§ 41808. Access to Prescription Monitoring Information by Patients. (a) A patient, or a patient's authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.

(b) A patient or a patient's authorized representative seeking access to prescription monitoring information described above shall submit a written request for information in person at the Department, or at any other place specified by the Department. The written request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements:

(1) The patient's full name and the full name of the patient's authorized representative, if applicable;

(2) The patient's date of birth;

(3) The patient's physical and mailing address, and the complete physical and mailing address of the patient's authorized representative, if applicable;

(4) The patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and

(5) The time period for which information is being requested.

(c) The patient or the patient's authorized representative shall produce a photographic identification card prior to obtaining access to the information described above. The patient or the patient's authorized representative shall allow photocopying of the identification.

(d) Prior to obtaining access to the information described above, authorized representatives shall produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or in the case of person holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative shall allow photocopying of the documents described above. The Department may verify the patient authorization by any reasonable means prior to providing the information to the authorized representative.

§ 41809. Access to Prescription Monitoring Information by Dispensers. (a) A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Department, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the dispenser's request.

(b) A dispenser who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an

authorization code. If the authorization code issued by the Department is lost or compromised, the dispenser shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

§ 41810. Access to Prescription Monitoring Information by Prescribers.

(a) A prescriber, or licensed health care practitioner duly authorized by a prescriber, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber's request.

(b) A prescriber, or licensed health care practitioner duly authorized by a prescriber, who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If

the authorization code issued by the Department is lost or compromised, the prescriber shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.

(d) A prescriber, or licensed health care practitioner duly authorized by a prescriber, shall, before writing a prescription for a controlled substance listed in Schedule II, III, IV, or V for a patient, obtain a patient utilization report regarding the patient for the preceding twelve (12) months from the computerized program established by the Department pursuant to § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67, if the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:

(1) The patient is a new patient of the prescriber; or

(2) The patient has not received any prescription for a controlled substance from the prescriber in the preceding twelve (12) months.

The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

§ 41811. Access to Prescription Monitoring Information by the Board. (a) The Board may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Board shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Board shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41812. Access to Prescription Monitoring Information by local, state, or federal law enforcement or prosecutorial officials. (a) A local, state, or federal law enforcement or prosecutorial official may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from a local, state, or federal law enforcement or prosecutorial official shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The

local, state, or federal law enforcement or prosecutorial official shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41813. Access to Prescription Monitoring Information by the authorized representatives of the Medicaid and Medically Indigent Program (MIP) within the Department of Public Health and Social Services. (a) An authorized representative of the Medicaid and Medically Indigent Program (MIP) may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the authorized representative of the Medicaid and Medically Indigent Program (MIP) shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The authorized representative of the Medicaid and Medically Indigent Program (MIP) shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41814. Access to Prescription Monitoring Information by the Medical Examiner . (a) The Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) The request from the Medical Examiner or a designee shall contain identifying information regarding the registrant or patient and the time period for

which the information is being requested. The Medical Examiner or a designee shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41815. Access to Prescription Monitoring Information by personnel of any vendor or contractor engaged by the Department. (a) Personnel of any vendor or contractor engaged by the Department may obtain any prescription monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.

(b) Program vendors or contractors engaged by the Department shall purge all prescription monitoring information more than six (6) years old.

§ 41816. Access to Prescription Monitoring Information by public or private entities for statistical, research, or educational purposes. A public or private entity may obtain any prescription monitoring information insofar as the information is necessary for statistical, research, or educational purposes, and insofar as information that can be used to identify a person has been removed. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

§ 41817. Designation of training programs. (a) Authorized dispensers shall attend a training course on the transmission, retrieval, and use of prescription monitoring information provided by the Department, which will be developed in consultation with the Advisory Committee, during the implementation phase of the Guam Prescription Drug Monitoring Program.

(b) Authorized prescribers who will be retrieving prescription monitoring information shall attend the training course indicated in § 41817(a) within these rules and regulations.

§ 41818. Confidentiality. Except as provided in this section, prescription monitoring information submitted to the Department shall be confidential and shall not be subject to public records laws. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in §§ 41808 to 41816 within these rules and regulations.

§ 41819. Criminal Penalties. (a) Pursuant to §§ 67.306 and 67.402(a)(3) of the Act, a dispenser who fails to submit the required information to the Department shall be guilty of a felony of the third degree.

(b) Pursuant to §§ 67.306 and 67.403(a)(4) of the Act, a dispenser who furnishes false or fraudulent information to the Department shall be guilty of a felony of the third degree.

§ 41820. Administrative Sanctions. The Department may pursue the suspension or the revocation of the registrant's CSR in accordance to § 67.304 of the Act for violating the terms of these rules and regulations, and may be subject to disciplinary action by any applicable governing entity.

§ 41821. Immunity. A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with these rules and regulations, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services.

§ 41822. Severability. If any provision of these rules and regulations, its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of these rules and regulations which can be given effect without the invalid provision or application, and to this end, the provisions of these rules and regulations are severable.

§ 41823. Effective Date. These rules and regulations shall be effective immediately upon compliance with Title 5 GCA, Chapter 9, Article 3.