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

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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.